Exhibit 88

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION ***THIS DOCUMENT RELATES TO ALL CASES***	**MDL NO. 16-2738 (MAS) (RLS)**

AMENDED RULE 26 EXPERT REPORT OF WILLIAM SAGE, MD, JD

Dated: November 15, 2023

William Sage, M.D., J.D.

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A. Qualifications

1. I am currently a tenured Professor of Law at Texas A&M University School of Law in Fort Worth, TX, a tenured Professor of Translational Medical Science at Texas A&M University School of Medicine, a professor by courtesy at the Bush School of Government and Public Service at Texas A&M University, and an Assistant Vice President in the Texas A&M University Health Science Center.

2. I received my A.B. degree *magna cum laude* in biochemical sciences from Harvard College in 1982. I received both my M.D. degree with research honors in anesthesia and critical care medicine and my J.D. degree with distinction from Stanford University in 1988. I hold an honorary doctorate from Universite Paris Descartes. I completed my medical internship at Mercy Hospital in San Diego and served one year of residency in anesthesiology and critical care medicine at The Johns Hopkins Hospital in Baltimore. I practiced corporate and securities law at O'Melveny & Myers in Los Angeles before entering the legal academy.

3. I have written over 200 articles, many of them peer reviewed, and have written or edited four books, including the Oxford Handbook of U.S. Health Law (2016). Many of these publications are relevant to the topic of this report, and reflect both analytical and empirical research.

4. I was recruited to Texas A&M University in 2022 to become the founding director of the Texas A&M University Institute for Healthcare Access. From 2006 to 2022, I was James R. Dougherty Chair for Faculty Excellence in the School of Law and Professor of Surgery and Perioperative Care in the Dell Medical School at the University of Texas at Austin, where I also served from 2006 to 2022 as that university's first Vice Provost for Health Affairs.

5. I was a tenured Professor of Law at Columbia until 2006, and have been a visiting law professor at Yale, Harvard, New York University (where I also was appointed a visiting professor of population health in the NYU Langone School of Medicine), Duke, Emory, and George Washington University.

6. I have taught classes in regulatory theory and public policy at Columbia Law School, the University of Texas School of Law, and Texas A&M University School of Law, classes in professional ethics and self-governance focusing on law and medicine, and a wide range of classes on health law and policy specifically.

7. I have served in advisory roles for governmental, academic, professional, and community organizations. I served as Cluster Leader, Health Care Working Group, on President Clinton's Task Force on Health Care Reform in 1993. Examples of present or recent leadership roles include: Editorial Board, *Health Affairs;* Fellows Council, The Hastings Center on Bioethics, of which I am an elected fellow; Board of Directors, ChangeLab Solutions; National Advisory Council, National Center on Medical-Legal Partnership.

8. Among other professional achievements, I am an elected member of the National Academy of Medicine, one of the three National Academies of Sciences. I have served the

National Academies in several voluntary capacities, including: Member, Board on Health Care Services; Member, Committee on the Future of Nursing, 2020-2030; Monitor, Report on *Regulating Medicines in a Globalized World;* Peer reviewer, Report on *Making Medicines Affordable: A National Imperative (2018)*. I am also an elected member of the American Law Institute, and I have served that organization as a volunteer advisor to the Restatement (Third) of Torts, focusing on proposed additions and revisions involving medical malpractice.

9. My expertise is in the science of policymaking, including the science of regulatory design. I have particular expertise in the regulation of health and safety, in information-based regulation, and in self-regulatory models. Self-regulation in which I am expert includes government-supervised health and financial self-regulation, corporate compliance and corporate governance, and the regulation of self-governing professions.

10. My compensation is $900/hour. I have not testified in any litigation in the last 4 years. My most recent Curriculum Vitae is attached as Exhibit A.

B. Methodology

11. I was asked to answer the following questions: (a) What are the regulatory practices and standards under which manufacturers of cosmetics operate? and (b) Did Johnson & Johnson comply with these standards in its general development, manufacture, marketing, and sale of talcum powder products?[1] I was not asked to give an opinion as to whether talcum powder products cause cancer.

12. I approached this analysis using the same processes and attention that I have applied in my professional and academic career. My research included searching and reviewing relevant laws and regulations, standards in the industry, peer-reviewed literature, publicly available information, and relevant corporate documents requested of counsel. Throughout this report, I cite specific documents; I have also attached a list of materials I reviewed as background even if not specifically cited in this report. My opinions were formulated based on this research and my professional knowledge, experience, and expertise.

C. Discussion

Federal regulation places responsibility directly on manufacturers to inform consumers of hazards and assure the safety of their products without extensive FDA participation or oversight.

13. Federal regulations for cosmetics have been in place for more than 80 years and have not changed significantly, even as a highly profitable cosmetics industry has grown and industrialized and globalized.

[1] As used in this report, “talcum powder products” means Johnson’s Baby Powder and Shower to Shower products containing talc as an ingredient.

14. Congress first granted the FDA regulatory authority over cosmetics as part of the 1938 Food, Drug and Cosmetics Act (FDCA). 21 U.S.C. § 361 et seq.

15. In 1933, FDA created a traveling exhibit to showcase "about 100 dangerous, deceptive, or worthless products that the FDA lacked authority to remove from the market"– the so-called "American Chamber of Horrors."[2] Public concern led to the passage of the 1938 FDCA.

16. Cosmetics regulation is small in scale and scope compared to drug and medical device regulation. There are only three statutory sections in the FDCA related to cosmetics, from which is derived all of FDA's authority. In Title 21 of the Code of Federal Regulation, regulations governing cosmetics comprise only one subchapter with five parts. In comparison, regulations governing drugs comprise two subchapters with fifty-one parts. And regulations governing medical devices comprise one subchapter with thirty-four parts.

17. The two central aspects of federal cosmetics regulation are (1) manufacturer informational obligations to consumers and (2) reliance on manufacturer and industry self-regulation. FDA has little direct involvement in these activities, and lacks routine authority to assure the safety of cosmetic products or ingredients.

18. The rudimentary character of the federal regulatory scheme for cosmetics has long been a topic of interest, with scholars and others acknowledging and debating the effectiveness of FDA's highly circumscribed authority over cosmetics under the FDCA. Hutt, Merrill, & Grossman, "Cosmetics," Food and Drug Law Cases and Materials (2014).

19. The FDA itself recognizes its limitations in effectively regulating cosmetics. Susan Mayne, Director of the Center for Food Safety and Applied Nutrition (CFSAN), testified in 2019 about the limitations of FDA's ability to regulate the industry.

20. Relevant, selected excerpts of testimony of Susan Mayne, Subcommittee on Health, House Committee on Energy and Commerce (Dec. 4. 2019):

> ". . . our authority over cosmetics has not modernized even as the industry has undergone rapid evolution."
>
> "Cosmetics firms are responsible for the safety of their products and ingredients. However, they are not required to provide any safety information to the Agency, even if requested by FDA during an inspection."
>
> "In recent years, our program for cosmetics is approximately $10 million and has represented about three percent of CFSAN's total $327 million budget."
>
> "Companies and individuals who market these products in the U.S. are responsible for the safety and labeling of their products. As stated above, the

[2] https://www.fda.gov/about-fda/fda-history-exhibits/80-years-federal-food-drug-and-cosmetic-act

> current law does not require cosmetics to be reviewed and approved by FDA prior to being sold to American consumers."
>
> "FDA's legal authority over cosmetics is different from our authority over other products we regulate, such as drugs, biologics, and medical devices."[3]

21. The cosmetics industry has equivocated between opposing stronger federal safety regulation and admitting its necessity, usually depending on trends in the state regulatory environment and in private litigation.

22. PCPC President Edward Kavanaugh said the following at the organization's 1995 Annual Meeting: "We begin [PCPC]'s second century with a great tradition of self regulation. And, as long as anyone can remember, our basic mission has been the same – keep government out of our backyard – no unnecessary or burdensome regulation."[4]

23. According to Hutt, Merrill, and Grossman: "The ability of the FDA to monitor and bring regulatory action with respect to claims for cosmetic products depends on the resources available to the agency for this purpose. Because of budgetary factors, FDA announced in 1998 that it was reducing the staff of the Office of Cosmetics and Colors by 50 percent and cutting back or eliminating many cosmetic regulatory programs. This reduction was so substantial that it propelled the cosmetic industry to request and obtain restoration by Congress of adequate funds to assure that the FDA has a credible cosmetic regulatory program."

24. Appearing on behalf of the PCPC before the Health Subcommittee of the Committee on Energy & Commerce, U.S. House of Representatives on March 27, 2012, Peter B. Hutt said: "It is essential … that FDA regulatory authority over cosmetics is firmly established as comprehensive and paramount. It is extremely important for the vitality of the industry that FDA establish national standards on safety that apply in every state. It is impossible to formulate innovative products if different safety standards apply in different states. And FDA authority is undermined if states create regulatory régimes for cosmetics that are different from FDA regulation of cosmetics."

25. On December 29, 2022, the Modernization of Cosmetics Regulation Act of 2022 ("Regulation Modernization Act") was signed into law by President Biden as part of the omnibus Consolidated Appropriations Act, 2023. The Regulation Modernization Act did not fundamentally alter cosmetics regulation, but reinforced existing obligations of manufacturers and the cosmetics industry by increasing FDA funding and oversight authority for reporting, product and facility registration, product recall, and safety substantiation. The Regulation Modernization Act recognizes through federal legislation the serious risks to life and health that cosmetics products can present, and the Regulation Modernization Act includes a section

[3] https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated
[4] PCPC_MDL00015232

instructing FDA to issue regulations standardizing testing procedures for asbestos in talc-containing cosmetics products.

Information and transparency for consumers are the fundamental regulatory obligations for food, drug, and cosmetics companies.

26. The 1906 Pure Food and Drug Act, which was the statute that began the modern era of federal regulation, primarily remedied concealment of actual or potential hazards to consumers in connection with widely sold, aggressively marketed "patent medicines."

27. Informational obligations were necessary in part because "patent medicine" manufacturers did not identify the ingredients in their products, treating them as trade secrets (few if any were actually patented, which would have required public disclosure). To this day, "fragrance" receives similar latitude in cosmetics regulation.

28. The Pure Food and Drug Act required ingredient disclosure for drugs and prohibited movement in commerce of misbranded or adulterated products. Adulteration and misbranding are distinct but related concepts; adulteration implies misbranding because a hazardous or unsanitary contaminant has been introduced without identification or warning to consumers about safe versus unsafe use. In addition to empowering FDA to sue to halt movement of offending products in commerce, adulteration and misbranding comprise part of the core focus of federal regulation on the informational obligations of manufacturers to consumers, which remains a foundation of cosmetics regulation.

29. Disclosure obligations remain principal duties of cosmetics manufacturers under federal law. "Under the Federal Food, Drug and Cosmetic Act (FD&C Act), cosmetic products and ingredients, with the exception of color additives, do not have to undergo FDA review or approval before they go on the market. Cosmetics must be properly labeled, and they must be safe for use by consumers under labeled or customary conditions of use. The law does not require cosmetic companies to share safety information with FDA."[5]

Talcum powder products contain or may contain ingredients that pose health hazards to consumers.

30. The label for Johnson's Baby Powder lists the ingredients as Talc and Fragrance. The label for Shower to Shower listed the ingredient as Zea Mays (Corn) Starch, Talc, Sodium Bicarbonate, Tricalcium Phosphate, Fragrance, Maltodextrin.[6] However, the actual constituents of Johnson and Johnson's talcum powder products include other potentially hazardous substances in varying amounts.

31. Non-asbestiform (platy) talc is the principal form of talc in talcum powder products. Talc particles are normally plate-like. This property is valued in cosmetics and powders because it provides softness and hydrophobicity. In 2010, IARC, based on a review of

[5] https://www.fda.gov/cosmetics/cosmetic-ingredients/talc
[6] Depending on the exact type of Shower to Shower, other ingredients may have been listed.

the scientific literature through 2006, classified the perineal use of talc-based powder (non-asbestiform) as possibly carcinogenic to humans (Group 2B). (IARC 2010)

32. Fibrous (asbestiform) talc is talc that forms as true mineral fibers, similar to asbestos. Asbestiform refers to the pattern of mineral growth in talc - not to the presence of other minerals – and should not be confused with talc that contains asbestos. Asbestiform talc is classified alongside asbestos in a 2012 IARC Monograph as carcinogenic to humans (Group 1) and causing ovarian cancer. Talc fibers occur in virtually all samples of Johnson's talcum powder products.[7]

33. Asbestos: Talcum powder also can and does contain levels of asbestos. Asbestos is carcinogenic to humans (Group 1) and known to cause ovarian cancer (IARC 2012). Johnson & Johnson's documents show the presence of asbestos in its talc products (Hopkins 28). Testing from Longo and Rigler show asbestos present in approximately 68% of historical Johnson & Johnson samples.[8] In October 2019, FDA found asbestos in a sample of Johnson's Baby Powder purchased online.

34. Fragrances: There is a mixture of 141 fragrance chemicals in Johnson's Baby Powder some of which are themselves mixtures of chemicals. There are 53 fragrances, some of which are also mixtures themselves, in Shower to Shower. These include potential and known carcinogens, toxins, and allergens (Expert Report of Dr. Crowley).

35. Heavy metals: Johnson's Baby Powder products have also been shown to contain nickel, chromium, and cobalt. (Pier Exhibit 47) Nickel and chromium are Group 1 carcinogens according to IARC. Cobalt is a Group 2B (possibly carcinogenic) substance according to IARC because of its inflammatory properties.

36. A brief history of the science relating to talcum powder and its association with ovarian cancer is included as Appendix 1.

Under the FDCA, Johnson & Johnson must take action to prevent adulteration of its products, inform consumers should adulteration occur, and mitigate risk through warning.

37. The FDCA applies its fundamental prohibition on "adulteration and misbranding" to cosmetics. Adulteration and misbranding are concepts integral to the overall focus of cosmetics regulation on informational obligations of manufacturers to consumers in order to prevent harm.

38. In the statement referenced above, Susan Mayne explained: "In general, except for color additives and those ingredients that are prohibited or restricted from use in cosmetics by regulation, a manufacturer may use any ingredient in a cosmetic, provided that the ingredient does not adulterate the finished cosmetic and the finished cosmetic is properly labeled."

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[7] Expert Report of William E. Longo, Ph D. & Mark W. Rigler, Ph. D 2019; ("The results showed that about 4% of the airborne talc would be classed as fibrous by the NIOSH method") (JNJ000231601).

[8] *Id.*

39. Under the FDCA, "[a] cosmetic shall be deemed to be adulterated . . . If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual . . . ." 21 U.S.C. § 361(a).

40. Adulteration empowers FDA to take legal action to prevent further movement in commerce of an adulterated product.

41. For some cosmetic ingredients, FDA has determined that certain ingredients are deleterious and by definition adulterants and should be prohibited in cosmetic products. See 21 C.F.R. §§ 700.11 (bithional); 700.13 (mercury); 700.14 (vinyl chloride); 700.15 (certain halogenated salicylanilides); 700.16 (zirconium); 700.18 (chloroform); 700.19 (methylene chloride); 700.27 (cattle materials).

42. Current literature suggests that there is no safe level of asbestos. Asbestos when present in talcum powder products is an adulterant because it is hazardous to human health.[9]

43. Adulteration implies misbranding, unless the product label is revised to identify the adulterant and warn consumers regarding safe use given the hazardous product contents (e.g., cautioning against inhalation or perineal administration for talcum powder products), and may require that the manufacturer cease production or sale if there is no assurance of safe usage.

44. In addition to asbestos, fibrous (asbestiform) talc, heavy metals, and certain fragrance chemicals could be considered adulterants in talcum powder products.

Cosmetics regulation requires manufacturers to inform consumers of <u>both</u> risk and uncertainty with respect to health hazards.

45. Risk is a known and quantifiable probability (statistical likelihood) of harm; uncertainty is lack of knowledge about the existence or magnitude of risk.

46. Information about risks of harm to health and safety is much better established for regulated drugs than for cosmetics because federal law requires manufacturers to submit comprehensive information from clinical trials in order to obtain FDA approval to sell and market drugs, and imposes obligations on drug manufacturers to surveil for and report post-marketing adverse events.

47. Cosmetics regulation lacks these requirements that manufacturers engage in a structured, FDA-supervised ascertainment of risk; as a result, the health hazards of cosmetics may be subject to considerable uncertainty even if the existence of some significant risk is

[9] Susan Mayne at the Cong. Hearing on the FDA in 2019. Sent clip.; Nicholson testimony (Forrest) NIOSH, *Workplace Exposure to Asbestos* 3 (1980); OSHA Position on the risk associated with asbestos exposure at the current PEL (May 13, 1999; https://www.fda.gov/news-events/fda-brief/fda-brief-fda-releases-final-report-talc-containing-cosmetic-products-tested-asbestos; https://www.niehs.nih.gov/health/materials/asbestos_508.pdf

proved. As detailed below, cosmetics regulation requires manufacturers to disclose uncertainty regarding safety.

48. The research described below establishes the existence of ovarian cancer risk from talcum powder products. Even if the precise quantification of risk is made difficult by factors such as multifactorial causality, variances in usage, and latency between exposure and cancer presentation, the existence of multiple studies finding risk indicates that talc is not proved safe. Both the risk and the uncertainty must be disclosed under the law.

Johnson & Johnson has known about risk and uncertainty regarding talc and ovarian cancer for decades.

49. Three basic facts have long indicated a potential health hazard from talcum powder products:

- Evidence that talc particles can reach the ovary (1971)
- Epidemiology suggesting an association (1982)
- Presence of asbestos and talc fibers in Johnson's Baby Powder (literature and testing)

50. Johnson & Johnson's resistance to the presence in talcum powder products of fibrous constituents that pose risk to human health is strikingly at odds with the factual history. Beginning in the 1960s, the scientific literature presented evidence of talcum powder containing asbestos and fibrous talc.[10] Johnson and Johnson testing results and internal discussions also demonstrate the presence of and concern about the presence of asbestos

[10] Cralley 1968 ("All of the 22 talcum products analyzed had an appreciable fiber content[s] ranging from 8% to 30% by count, with an average of 19%. The fibrous material was predominantly talc but probably contained minor amounts of tremolite, anthophyllite, and chrysotile as these are often present in fibrous talc mineral deposits."; Rohl 1974 ("Since the mining of talc rock almost invariably includes the mining of asbestos as well, the asbestos contaminant may be carried over into the consumer products and thus introduce the risk of asbestos disease."); Rohl 1976 ("Of the 20 body powders, baby powders, facial talcums and one pharmaceutical talc tested, 10 contained detectable amounts of tremolite and anthophyllite, principally asbestiform…Fibrous talc is more pathogenic than platy talc."); Lockey 1981 (Talc frequently exists in mineralogically complex deposits that are contaminate with quartz and/or asbestos-forming minerals, amphibole (tremolite and anthophyllite) and serpentine…Tal free of asbestiform minerals also exists in fibrous form…"The complexity of talc deposits is important when considering the potential health effects of the mineral"); Paoletti 1983 ("Samples of talc powders used as excipients in pharmaceutical and cosmetic preparations demonstrated fiber contents up to 30% of total particles. About a half of the talc powders revealed the presence of asbestos"); Blount 1991 ("A baby powder [confirmed Johnson's Baby Powder in deposition] showed 0.4 to 0.8 million amphibole particles per milligram.")

and talc fibers.[11] Drs. Longo and Rigler tested historical samples (1960s through the early 2000s) of Johnson's Baby Powder and Shower to Shower, finding 68% of samples testing positive for amphibole asbestos and 98% positive for fibrous talc.[12] A brief timeline of important historical events indicating a potential health hazard follows.

51. In 1948, Johnson & Johnson Laboratories recognized the inflammatory effects of talcum powder in the peritoneal cavity.[13]

52. In 1952 Johnson & Johnson submitted a patent application for a "nonirritating" cornstarch alternative to talc.[14]

53. In 1958, asbestos was found in Johnson's Baby Powder. (Asbestos was known to cause lung cancer since the 1930s and was suspected to cause ovarian cancer since the 1960s).[15]

54. In 1971, Henderson found talc in ovarian tumors.[16]

55. In 1976, Industry (CTFA) developed the J4-1 method of asbestos detection as a self-regulatory standard for asbestos testing.[17]

56. In 1982, Cramer published the first epidemiological study describing an association between genital talcum powder use and ovarian cancer.[18]

57. In 1995, condom manufacturers voluntarily removed talc from their products because of ovarian cancer concerns.[19]

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[11] Exhibit 28, Deposition of John Hopkins, Ph.D., In Re: Talcum Powder Prod. Liab. Litig., MDL No. 2378" 2018; "Exhibit 47, Deposition of Julie Pier, In Re: Talcum Powder Prod. Liab. Litig., MDL 2738" 2018

[12] Expert Report of William E. Longo, Ph D. & Mark W. Rigler, Ph. D, In Re: Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Products Liability Litigation Dated 2.2.2019

[12] Eberl, J. J., et al. Comparative Evaluation of the Effects of Talcum and a New Absorbable Substitute on Surgical Gloves. Am.J Surg. 75, No. 3 (March 1948): 493–97.

[14] P-321

[15] 30(b)(6) Deposition and Exhibits of John Hopkins Taken on 8.16.18, 8.17.18, 10.17.18, 11.05.18, Exhibit 28

[16] Henderson, W. J., et al. Talc and Carcinoma of the Ovary and Cervix. The Journal of Obstetricsand Gynaecology of the British Commonwealth 78, No. 3 (March 1971): 266–72.

[17] PCPC_MDL00007392

[18] Cramer, D. W., et al. Ovarian Cancer and Talc: A Case-Control Study. Cancer 50, No. 2 (July15, 1982): 372–76.

[19] PCPC MDL00062175

58. In 1999, Ness proposed a mechanism by which talc and asbestos could cause ovarian cancer.[20]

59. In 2008, IARC designated non-asbestiform talc as possibly carcinogenic.[21]

60. In 2012, IARC designated asbestos and fibrous talc as carcinogenic, including with respect to ovarian cancer.[22]

61. In 2019, FDA found asbestos in Johnson's Baby Powder.[23]

Cosmetics regulation requires manufacturers to disclose all substantial risks, without regard for purported benefits.

62. Under the FDCA, "[t]he term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap." 21 U.S.C. § 321(i)

63. As defined by the law, cosmetics do not have any therapeutic or medicinal benefit. However, cosmetics and cosmetic ingredients may carry a significant risk to human health.

64. For cosmetics, the risk alone determines the manufacturer's obligations to inform consumers or to limit sale or to withdraw a product from the market. This is unlike drugs, for which the comparison of risk to benefit determines whether a drug will be approved by the FDA for sale and marketing, although safety labeling (warnings) is required for drug risks regardless of benefits.

The FDCA's prohibition on misbranding requires Johnson & Johnson not to mislead consumers, to inform consumers of specific attributes of its products, and to warn of both risk and uncertainty, duties that cosmetics-specific FDA regulations have expanded and clarified.

65. Federal law places heightened consumer-facing informational requirements on manufacturers because it is the central regulatory method employed for cosmetics.

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[20] Ness RB, Cottreau C. Possible role of ovarian epithelial inflammation in ovarian cancer. J Natl Cancer Inst. 1999 Sep 1;91(17):1459-67. doi: 10.1093/jnci/91.17.1459. PMID: 10469746.; IMERYS 013188

[21] Langseth, H., et al. Perineal Use of Talc and Risk of Ovarian Cancer. J. Epidemiol. Comm.Health 62, No. 4 (April 2008): 358–60; International Agency for Research on Cancer (IARC), Carbon Black, Titanium Dioxide, andTalc, IARC Monographs No. 93., (2010).

[22] International Agency for Research on Cancer (IARC), Arsenic, Metals, Fibres, and Dusts, IARCMonographs No. 100c., (2012).

[23] Dyer O. Johnson & Johnson recalls its Baby Powder after FDA finds asbestos in sample. BMJ. 2019 Oct 21;367:l6118. doi: 10.1136/bmj.l6118. PMID: 31636060.

66. Manufacturers bear near-total responsibility for making cosmetics information understandable and useful to consumers. Unlike drug regulation, only very rarely is there a physician or other expert intermediary between a cosmetics product and the consumer, and the FDA does not regulate the voluntary relationship between cosmetics companies and such intermediaries.

67. Some cosmetics products are labeled "professional use only" and sold to cosmetologists or similar professionals; these have lesser labeling requirements under federal law than apply to products such as baby powders sold directly to consumers.

68. According to Hutt, Merrill, and Grossman, it "is common practice for cosmetic companies to provide the components of their products to dermatologists to use in skin patch tests on patients to determine sensitivity to particular substances. … and FDA encourages this practice. 21 C.F.R. 720.4(b)(4)."

69. Under the Federal Product Labeling Act (FPLA), which is enforced by the Federal Trade Commission with respect to many consumer products, cosmetic manufacturers must disclose basic information about their products.

70. FDA requires manufacturers to label cosmetics with specific information so as to be apparent to consumers. See 21 C.F.R. §§ 701.1 et seq.

71. Under the FDCA, 21 U.S.C. § 362, "A cosmetic shall be deemed to be misbranded—(a) If its labeling is false or misleading in any particular." Labeling includes information that accompanies a product in commerce, even if not on its immediate container or packaging, and may include manufacturer websites.

72. Johnson & Johnson's website includes a prominent and easily searchable web page titled 5 Important Facts About Talc Safety.[24]That web page contains several assertions stating or implying the safety and purity of talcum powder products that are misleading in light of the scientific studies detailed above.

73. Among other things, the Johnson & Johnson web page misleads consumers to equate talcum powder products with "pure" talc, fails to mention asbestos or other possible adulterants, states definitively that "talc" is safe and does not cause cancer, suggests untruthfully that FDA has determined talcum powder products to be safe, and suggests untruthfully that regulatory bodies in other countries have reached similar conclusions. In particular, the web page omits any suggestion that uncertainty exists with respect to the overall safety or carcinogenic risk of talcum powder products – a conclusion at odds with research science.

[24] Johnson & Johnson. (2018, December 15). 5 Important Facts About the Safety of Talc. Content Lab U.S. https://www.jnj.com/our-products/5-important-facts-about-the-safety-of-talc

Cosmetics manufacturers have both general and specific duties under federal law to warn consumers of risk and uncertainty.

74. Cosmetics manufacturers must warn consumers of possible health hazards, with the law applying a low threshold for disclosure of risk and uncertainty because cosmetics have no offsetting health benefits and because studies of cosmetics are infrequent and poorly funded compared to drugs. 21 C.F.R. §§ 740.1 et seq.

75. 21 CFR §740.1(a) states that a cosmetic product's label "shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product."

76. According to Hutt, Merrill, and Grossman, FDA has determined under Sections 201(n) and 602(a) of the FDCA that the failure of a cosmetics label to bear an appropriate warning constitutes misbranding.

77. Notwithstanding the scientific research summarized above, Johnson & Johnson has not modified its label for talcum powder products to specify that perineal use is unsafe.

78. FDA regulation at 21 C.F.R. § 740.1 (b) states:

> (b) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish or amend, under subpart B of this part, a regulation prescribing a warning for a cosmetic. Any such petition shall include an adequate factual basis to support the petition, shall be in the form set forth in part 10 of this chapter, and will be published for comment if it contains reasonable grounds for the proposed regulation.

79. Johnson & Johnson's reliance on FDA's 2014 denial of two citizen's petitions for specific warning language as relieving them of a regulatory duty to warn of risk or uncertainty (discussed in detail below) is misplaced.

80. That denial letter to the petitioning organization concluded merely that, in FDA's view, the evidence was "insufficient for FDA" to prescribe as mandatory the "definitive language" that had been requested. A denial by the FDA to prescribe a specific requested warning under 740.1(b) does not negate the manufacturer's responsibility to warn under 740.1(a), which is a core obligation at the heart of the FDCA's regulatory design.

81. Cosmetics manufacturers are specifically required to disclose uncertainty regarding product safety, even if a risk has not been definitively established or quantified. 21 C.F.R. §740.10(a) sets forth FDA regulations regarding labeling when safety is not adequately substantiated by the manufacturer:

> Labeling of cosmetic products for which adequate substantiation of safety has not been obtained.

> (a) Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel:
>
> *Warning*—The safety of this product has not been determined.

82. 21 C.F.R. §740.10(b) emphasizes that manufacturers bear a continuing obligation to disclose uncertainty as new information becomes available, even if that information is not conclusive, subject to a narrow exception if three criteria are all met:

> (b) An ingredient or product having a history of use in or as a cosmetic may at any time have its safety brought into question by new information that in itself is not conclusive. The warning required by paragraph (a) of this section is not required for such an ingredient or product if:
>
> (1) The safety of the ingredient or product had been adequately substantiated prior to development of the new information;
>
> (2) The new information does not demonstrate a hazard to human health; and
>
> (3) Adequate studies are being conducted to determine expeditiously the safety of the ingredient or product.

83. Johnson & Johnson has not applied a "safety not determined" label to its talcum powder products notwithstanding lack of prior substantiation for safety and new information repeatedly demonstrating a hazard to human health. Expeditious and definitive studies to determine safety are impossible given long latency for carcinogenesis and other research challenges. There is not a single part of the three-part test for an exception to disclosure that has been met and evidence of uncertainty regarding product safety is abundant.
84. The Regulation Modernization Act retains consistency with this established law, clarifying by addition but not materially altering manufacturers' direct accountability and their obligation to substantiate in accordance with science. It provides in an added Section 608 of the FDCA : "A responsible person for a cosmetic product shall ensure, and maintain records supporting, that there is adequate substantiation of safety of such cosmetic product." The same section also clarifies that "The term 'adequate substantiation of safety' means tests or studies, research, analyses, or other evidence or information that is considered, among experts qualified by scientific training and experience to evaluate the safety of cosmetic products and their ingredients, sufficient to support a reasonable certainty that a cosmetic product is safe."

In addition to published literature reporting the risks of cancer, international assessments questioning the safety of talcum powder products also obligated Johnson & Johnson to comply with its specific regulatory duty to warn consumers regarding uncertainty and cancer risk.

85. Johnson & Johnson has a legal duty to take account of "new information" putting the safety of its talcum powder products in question, even if the information is itself not conclusive. The general term "information" encompasses analyses and interpretations of existing scientific research, in addition to any new scientific research, and includes the findings of an international public agency such as the International Agency for Research on Cancer (IARC) or a national regulator outside the United States such as Health Canada.

86. The International Agency for Research on Cancer (IARC) classified talc not containing asbestiform fibers as possibly carcinogenic in 2010 and asbestos, including asbestiform (fibrous) talc, as carcinogenic including ovarian cancer.

87. IARC Monograph 93, published in 2010 based on a literature review through 2006, covers "Talc not containing asbestiform fibers". The Monograph states that "asbestiform refers to a habit (pattern) of mineral growth and not to the presence of other minerals" and that "asbestiform talc must not be confused with talc that contains asbestos." The IARC Working Group acknowledged that the content of body powders has changed over time (although data that document this are limited), but that "amphibole was voluntarily reduced to less than detectable levels, as least in Western Europe and the USA" in the mid-1970s. IARC concluded that the perineal use of talc-based powder is possibly carcinogenic to humans (Group 2B).

88. IARC Monograph 100C, published in 2012, concludes that "All forms of asbestos are carcinogenic to humans (Group 1). Asbestos causes mesothelioma and cancer of the lung, larynx, and ovary."

89. IARC Monograph 100C covers both asbestos and fibrous talc ("The conclusions reached in this Monograph about asbestos and its carcinogenic risks apply to these six types of fibres wherever they are found, and that includes talc containing asbestiform fibres") The Monograph provides a detailed discussion of occupational exposure to asbestos and talc in which inhalation presents the primary exposure, but this is not the only purpose. IARC also addresses "Exposure of the General Population:

> Consumer products (e.g. cosmetics, pharmaceuticals) are the primary sources of exposure to talc for the general population. Inhalation and dermal contact (i.e. through perineal application of talcum powders) are the primary routes of exposure."

90. The IARC Working Group concluded that a causal relationship between asbestos (including talc containing asbestiform fibers) and cancer of the ovary is clearly established. The biological plausibility for the association was derived in part from the

finding of asbestos fibers in the ovaries of women with potential for exposure to asbestos. The molecular pathogenesis (in the respiratory tract), over the course of a long latent period, included multiple genetic and molecular alterations involving activation of cell growth, gene mutations, resistance to apoptosis, genetic instability, generation of reactive oxygen species, and direct DNA damage.

91. Health Canada undertook a comprehensive assessment of talc's safety in cosmetics, with a draft of its findings published in December 2018 and its final assessment released in May 2021. Health Canada is the department of the Government of Canada that oversees national health policy. Health Canada is a regulatory agency that is responsible for product safety, drugs and health products, environmental and workplace health, food and nutrition, Canada's health system, prevention and education on health-related issues, and health science and research.[25]

92. With respect to human health, the Health Canada screening assessment includes the consideration of information on chemical properties, environmental fate and behavior, hazards, uses, and exposures, including additional information submitted by stakeholders. Relevant data were identified up to October 2020. Empirical data from key studies, as well as results from models, were used to reach conclusions.[26] The human health portion of the review underwent external peer review.[27]

93. Like the cosmetic industry's CIR review described below, the Health Canada assessment focused on health effects associated with cosmetic- and pharmaceutical-grade talc and not on potential impurities, such as asbestos. The Assessment identified no critical health effects via the oral or dermal routes of exposure.

94. With regards to perineal exposure, Health Canada reached a very different conclusion from the cosmetic industry's CIR Panel:

> [A]nalyses of the available human studies in the peer- reviewed literature indicate a consistent and statistically significant positive association between perineal exposure to talc and ovarian cancer. The available data are *indicative of a causal effect*. Given that there is potential for perineal exposure to talc from the use of certain self-care products (e.g., body powder, baby powder, diaper and rash creams, genital antiperspirants and deodorants, body wipes, bath bombs, bubble bath), a potential concern for human health has been identified.

95. The Health Canada report reinforces the IARC conclusions, stating: "Overall, there is a high degree of consistency in the epidemiological studies across several decades

[25] www.canada.ca/en/health-canada.html
[26] Health Canada. (2021). Health Canada Screening Assessment: Talc. Canada: Minister of Environment and Climate Change at 1.
[27] Health Canada at 2.

conducted in different parts of the world. Although there are uncertainties related to bias, there is confidence in the robustness of the available database for use in characterizing ovarian cancer risk attributed to talc exposure. Furthermore, the available data are indicative of a causal relationship."

96. Also from Health Canada: "Based on the available data, ovarian cancer was identified as a critical health effect for the perineal route of exposure to talc. While animal models are generally inadequate to assess ovarian cancer risk, the available animal studies (noting inflammatory response to talc and the ability of talc particles to migrate up the reproductive tract) support biological plausibility and results were consistent with a possible human mode of action for cancer development. The database is large, and while cohort and case-control studies generally gave different results, the overall database provides adequate information to assess the risk of ovarian cancer due to talc exposure. There is the potential for perineal exposure to talc from the use of various self-care products (e.g. body powder, baby powder, diaper and rash creams, genital antiperspirants and deodorants, body wipes, bath bombs, bubble bath)."

97. Health Canada notes that its "[c]haracterization of ovarian cancer risk is qualitative in nature as a clear dose response for ovarian cancer could not be derived from the available literature" but concludes that "[d]ata from meta-analyses of epidemiological studies indicate a consistent and statistically significant positive association between perineal exposure to talc and ovarian cancer." (citing Huncharek et al. 2003; Langseth et al. 2008; Terry et al. 2013; Berge et al. 2018; Penninkilampi and Eslick 2018; Taher et al. 2019).

98. Health Canada concludes: "Although some authors note concerns with regard to bias in the literature, considering the available lines of evidence, the current data are indicative of a causal effect. Given that there is the potential for perineal exposure to talc from the use of various self-care products, a potential concern for human health has been identified."

99. The IARC and Health Canada reports discussed above evaluated the evidence of risk that had been published over decades. These concerns clearly established Johnson & Johnson's obligation to place on its talcum powder products the FDA-mandated warnings of "safety not determined" and "may be associated with a health hazard". Although Johnson & Johnson has stopped manufacturing its talcum powder products in the United States and Canada, and has announced its intention to stop manufacturing elsewhere, no information regarding a possible association with ovarian cancer has been provided to consumers. Without detailed explanation, Johnson & Johnson has announced it will use cornstarch rather than talc in the manufacture of baby powder.

Cosmetics safety depends on self regulation but, unlike drug regulation, cosmetics self-regulation is not supervised by the FDA or any other government agency.

100. Federal cosmetics regulation has always lagged federal regulation of drugs. Drug regulation has advanced to include direct, substantive oversight of manufacturer conduct by government agencies with pre-market approval of drugs only if safety and

effectiveness have been established. Cosmetics regulation, by contrast, has remained grounded in the informational obligations detailed above, with manufacturers retaining substantive responsibility, unsupervised by government, for substantiating safety through necessary testing and surveillance.

101. According to FDA's website, "Companies and individuals who manufacture or market cosmetics have a legal responsibility to ensure the safety of their products. Neither the law nor FDA regulations require specific tests to demonstrate the safety of individual products or ingredients. The law also does not require cosmetic companies to share their safety information with FDA."[28] The Regulation Modernization Act replaces prior voluntary reporting of safety events with a mandatory reporting system, and authorizes funding for that activity that had not previously been available to FDA. The Regulation Modernization Act does not require specific tests, although it instructs FDA to issue regulations regarding standardized testing for asbestos in talc-containing cosmetic products.

102. The fundamental self-regulatory obligation of cosmetics manufacturers is set forth at 21 CFR §740.10: "Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing."

103. Federal regulations prior to the Regulation Modernization Act stated: "FDA has no authority under the FD&C Act to order a recall of a cosmetic, although it can request that a firm recall a product."[29] FDA has been able to initiate legal action to remove an adulterated or misbranded cosmetic product from commerce but even then has not been able to do so in a self-executing manner. Asbestos-contaminated baby powder and other asbestos-contaminated cosmetics were voluntarily recalled after FDA requests. The Regulation Modernization Act confers new authority on FDA to order cosmetic product recalls.

104. Public interest groups such as the Environmental Working Group have testified before Congress that the FDA "has little authority to review or restrict chemicals in cosmetics." Testimony of Scott Faber, Senate Committee on Health, Education, Labor and Pensions (Sept. 22, 2016). The Regulation Modernization Act enhances this authority, but reaffirms and retains the primacy of manufacturer accountability for safety.

105. Self-regulation follows established models: It can consist of informal norms, industry codes of conduct, firm-based self-regulation (e.g.., corporate compliance and ethics programs, sometimes required by law or established by agreement with state or federal enforcers), statutory self-regulation (e.g., self-governing professions such as law or medicine), and supervised self-regulation (e.g., financial self-regulation supervised by the Securities and Exchange Commission). (M. Priest, Five Models of Self-Regulation)

[28] https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fda-authority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated

[29] https://www.fda.gov/cosmetics/cosmetics-recalls-alerts/fda-recall-policy-cosmetics.

106. "Supervised self-regulation" has several general characteristics that were lacking for cosmetics under the FDCA prior to 2023, when the Regulation Modernization Act took effect. These include mandatory registration with and reporting to the supervising government agency, submission of evidence of quality and safety for supervising agency approval, establishment of standards of manufacture and conduct, compliance with standards subject to supervisory inspection or audit with the potential for discipline, post-marketing surveillance and reporting to the supervisor of complaints or harms.

107. Federal drug regulation under the FDCA follows a supervised self-regulatory model with initial authorization to market, approved informational labelling and warnings, standardized manufacturing practices, and other forms of manufacturer conduct requiring regulatory approval and being subject to continuing FDA oversight and correction.

108. Cosmetics self-regulation employs a mixture of informal norms, industry codes of conduct, and firm-based regulation, with a limited number of specific regulatory directives. For example, FDA regulation that requires cosmetics manufacturers to "substantiate safety" of their products and ingredients prior to marketing is the unsupervised and less detailed analog of pre-marketing approval by a supervising regulator. The Regulation Modernization Act affirms and reinforces this regulatory approach, adding only limited forms of FDA supervisory oversight such as mandatory safety reporting and cosmetic product recall authority.

Johnson & Johnson claims that it has a robust ethics and compliance program of firm-based self-regulation that goes above and beyond the legal requirements.

109. Johnson & Johnson claims to be the world's largest and most diversified healthcare company. (https://www.jnj.com/about-jnj) Johnson & Johnson therefore has the resources and experience to perform at the highest levels of firm-based self-regulation, yet it has failed to establish or maintain the safety of its talcum powder products.

110. Janssen Pharmaceutical Companies of Johnson & Johnson produces pharmaceuticals in six important therapeutic areas: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology and Pulmonary Hypertension.

111. Johnson & Johnson Medical Devices Companies produce devices used in Orthopedics (artificial joints, screws, plates, nails, and implants, spinal implants, cranio-maxillofacial devices, power tools, and biomaterials), Surgery (sutures, biosurgery technologies, surgical stapling and endocutter technologies), Interventional (technologies for arrythmias and strokes), and Vision (products for myopia, farsightedness, astigmatism, beauty and performance, glaucoma, dry eye, and cataracts.

112. Johnson's Baby Powder is produced by Johnson & Johnson Consumer Inc. in its Consumer Health Division. That part of the company claims to be "driven to improve the

personal health of people everywhere," delivering "products that are rooted in science and endorsed by professionals."

113. Its website continues: "Our differentiated portfolio of iconic brands, including Tylenol, Zarbee's, Neutrogena, Aveeno, Listerine, OGX, and Johnson's, delivers life-enhancing, first-to-market innovation. By combining the power of science with meaningful human insights and digital-first thinking, we help more than 1.2 billion people live healthier lives every day, from their very first day…. We are on a mission to ensure that all Johnson & Johnson Consumer Health brands will achieve…full transparency on ingredients so consumers can make informed choices."

114. With the large number and wide variety of consumer and healthcare products as described above, Johnson & Johnson should have extensive knowledge and experience in regulatory matters. In its "Position on Ethics and Compliance," Johnson & Johnson says as much: "Ensuring compliance with all relevant laws and regulations is a fundamental duty of corporations and their governance." In addition, it claims to be "committed to maintaining the highest level of integrity and ethical and compliant conduct." (Johnson & Johnson Position on Ethics and Compliance)

115. Johnson & Johnson is well aware of regulatory best practices that could guide its self-regulatory activities. It has extensive knowledge of and experience with FDA's drug regulatory standards and practices. It observes and understands the high consumer expectations reflected in the adoption of new state laws, such as California's Safe Cosmetics Program. It complies with other countries' regulatory approaches (e.g., regarding styrene in connection with fragrance ingredient disclosure) but it continues to promote talcum powder products as safe in the United States.

Contrary to its representations regarding ethics and compliance, Johnson & Johnson has resisted or suppressed testing and standards for testing talc-based products instead of encouraging them.

116. As stated previously, beginning in the 1960s, the scientific literature presented evidence of talcum powder containing asbestos and fibrous talc. Johnson & Johnson testing results and internal discussions also demonstrate the presence of and concern about the presence of asbestos and talc fibers.

117. On July 8, 1971, following reports of asbestos in talc, Johnson & Johnson briefed FDA on the company's process for selection and testing of talc used in its products.[30] At this meeting, Johnson & Johnson claimed it could detect "1% added asbestos" and promised to provide FDA with data to support the safety of its talc.

118. On September 28, 1973, the FDA published a proposed regulation for asbestos in talc in the Federal Register, which called for a 99.9% purity for amphibole asbestos fiber and 99.99% for chrysotile and proposed the use of a polarized microscope.

[30] JNJ 000284107

119. In 1974, Johnson & Johnson claimed in a letter to the FDA that "a substantial safety factor can be expected with talc containing 1% w/w asbestos fibers[] . . . [and] methods capable of determining less than 1% asbestos in talc are not necessary to assure the safety of cosmetic talc.

120. On December 17, 1974, Johnson & Johnson sent a letter to PCPC about talc testing standards: "The talc task force has completed the process of development of analytical procedures for determining the presence of chrysotile and tremolite in talc. We believe it is critical for the C.T.F.A. to now recommend these methods to the F.D.A. before the art advances to more sophisticated techniques with higher levels of sensitization."[31]

121. On January 30, 1975, Johnson & Johnson held an internal meeting to discuss issues related to talc.[32] In this meeting, "[f]inal recommendations were forwarded by the Task Force . . . [and] [l]imits of detectability in cosmetics talcs have been determined to be 0.5 – 1.0%."

122. According to Hutt, Merrill, and Grossman, in March 1975, FDA announced that the proposed regulations for asbestos content in talc would be delayed, in part because the proposed method was "difficult to use, laborious, and not practical for its intended purpose."[33]

123. In 1976, the CTFA published the J4-1 method for detecting "Asbestiform Amphibole Minerals in Cosmetic Talc."[34] This method became the industry standard for testing for asbestos in talc and 1976 is widely cited in scientific literature as the date after which no asbestos has been present in talc because of these specifications.[35] The peculiarity of retaining without reconsideration for nearly half a century a testing method clearly at odds with current science is repeatedly noted in the White Paper issued in late 2021 by the federal government's Interagency Working Group on Asbestos in Consumer Products.[36]

124. At no point has the FDA issued any regulation dictating testing specifications for detecting asbestos in talc and instead has relied on industry substantiation of safety. Recognizing the inadequacy of this situation given industry's poor track record of incorporating established science into testing talc-based cosmetic products for potentially

[31] JNJ000267138
[32] JNJ000025189
[33] Hutt, P.B. "A History of Government Regulation of Adulteration and Misbranding of Cosmetics," Chapter 1 in Cosmetic Regulation in a Competitive Environment (2000); Rules and regulations. Fed Regist 1975; 40: 11865–11869
[34] PCPC_MDL00007392
[35] *See, e.g.*, Fiume et al. (2015) ("In 1976, specifications for cosmetic talc requiring that no detectable fibrous, asbestos mineral be present were developed. Therefore, this report will only address the safety of talc that does not contain asbestos.")
[36] Interagency Working Group on Asbestos in Consumer Products (IWGACP), White Paper: IWGACP Scientific Opinions on Testing Methods for Asbestos in Cosmetics Products Containing Talc (Dec. 2021).

harmful components or contaminants, the Regulation Modernization Act requires FDA to develop and issue regulations for asbestos testing.

125. In sum, Johnson & Johnson manipulated asbestos testing and associated publicity so that "none detectable" would be interpreted as "none," distancing itself from allegations of asbestos contamination but never actually eliminating asbestos contamination.

CIR appears and purports to be a supervised. independent self-regulatory testing and evaluation body, but it is not supervised by FDA and its evaluations favor industry interests.

126. The Cosmetic Ingredient Review (CIR) was formed by PCPC (then CTFA) in 1976. According to PCPC President Edward Kavanaugh in 1995: "CIR began in 1976 in response to Congressional concerns raised about the safety of cosmetic ingredients, and the need to ensure a totally unbiased review of safety. That could have meant federal regulation. CIR is a key reason why we have voluntary, self-regulation instead." [PCPC_MDL00015248]

127. CIR is comprised of staff members and an expert panel and is overseen by a Steering Committee. [CIR Procedures, IMERYS 118788]. CIR is funded by PCPC, shares office space with PCPC, and CIR staff members are paid by PCPC. CIR expert panel members are selected by the Steering Committee, which includes representatives from the cosmetic industry as well as PCPC.

128. FDA has no regulatory authority with respect to CIR, other than to interact voluntarily with it. FDA cannot instruct CIR on what to review. FDA cannot instruct CIR on how to conduct its reviews. FDA cannot reject a CIR review finding.

129. CIR reviews ingredients based on a priority list and ultimately issues conclusions in a final report that is then published in the International Journal of Toxicology. As part of its conclusions, CIR categorizes ingredients in one of the following categories:

- Safe as used
- Safe with qualifications
- Zero uses
- Insufficient data
- Prohibited/Restricted by FDA
- Unsafe
- Use not supported

130. CIR overwhelmingly confirms safety, and only rarely opines that insufficient data exist to make a determination or that an ingredient is unsafe. In combination with the fact that the "safety not determined" warning required by FDA is almost never used, it seems that one of the most useful self-regulatory functions CIR could perform has been neglected by it.

131. According to CIR Procedures, "'Safe' or 'safety' means no evidence in the available information that demonstrates or suggests reasonable grounds to suspect a hazard to the publish under the conditions of use that are now current or that might reasonably expected in the future, . . ." Since its inception, CIR has reviewed thousands of cosmetic ingredients but only determined that 12 are unsafe.[37]

132. FDA has only banned 11 cosmetic ingredients. 21 C.F.R. § et seq. 700.11 et seq.[38] The European Union, in comparison, has banned the use of 1,644 cosmetic ingredients.[39]

133. In an industry meeting in 2000, the meeting notes reflect that "input from outside attendees is welcome at the meetings [of the CIR] and can have a major impact on the outcome of the deliberations." [PCPC0082734] During and prior to the talc review process, industry monitored and communicated with CIR about the review. In a May 2005 email, a Johnson & Johnson employee notes that talc is on the CIR "priority list." [JNJ 000388747]

134. Imerys Talc (formerly Luzenac and Rio Tinto) hired the Center for Regulatory Effectiveness (CRE) as a consultant on talc, and as part of these consulting services, William Kelly of the CRE communicated with and provided information to the CIR during their review process.

135. In September 2006, Rich Zazenski circulated a summary from William Kelly about a recent CIR meeting Mr. Kelly attended. The summary notes that "CIR staff has begun gathering information for the talc Scientific Literature Review, but has not begun writing it." [IMERYS-A_0002859]

136. On April 18, 2008, William Kelly reported that he attended a CIR meeting and talked with CIR staff and the CIR Director about the talc review. [IMERYS 280713]

137. On August 4, 2009, William Kelly submitted a letter with commentary and a bibliography to CIR Director Alan Anderson. [IMERYS 275357]

138. On October 7, 2011, CIR Director Alan Anderson emailed Monice Fiume of the CIR and directed her to reach out to William Kelly to ask that he submit information on talc so it could be included in the CIR's Scientific Literature Review. [PCPC_MDL00017752]

139. On October 14, 2011, William Kelly relayed to Shripal Sharma at Imerys Talc that he spoke with Monice Fiume of the CIR, "the lead on the talc review at CIR[.]"[40]

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[37] https://cir-safety.org/sites/default/files/U-breakout-092020r.pdf
[38] https://www.fda.gov/cosmetics/cosmetics-laws-regulations/prohibited-restricted-ingredients-cosmetics
[39] https://ec.europa.eu/growth/tools-databases/cosing/pdf/COSING_Annex%20II_v2.pdf
[40] Monice Fiume holds B.S. and M.B.A. degrees, but no advanced degrees in any scientific field. https://www.cir-safety.org/about

According to Kelly, she told him that "[s]he has not yet started on the SLR [Scientific Literature Review], and does not think that it will be released for public comment until mid-2012 at the earliest . . . ." but that "CIR would welcome any input from industry on the review at any time, including now." [IMERYS 065205]

140. In December 2012 and February 2013, CIR released draft reports on the Safety Assessment of Talc as Used in Cosmetics. [IMERYS 173648] On April 12, 2013, the CIR released its Final Report on the Safety Assessment of Talc as Used in Cosmetics. [2013 CIR Final Report]

141. The only comments received at any stage in the review process were from cosmetic industry companies, consultants, or PCPC. [IMERYS 173648] Following the submission of the final report in 2013, industry consultant William Kelly stated in an email that "the CRE engineered the CIR report from the outset…" [MBS-CRE 271]

142. In 2015, the CIR's assessment was published in the International Journal of Toxicology. Fiume et al. Safety Assessment of Talc as Used in Cosmetics, 34 Int'l J. Tox. 665 (2015).[41]

143. The CIR Panel commented that the safety of talc had been the subject of debate through the years, partly because the "relationship between talc and asbestos is commonly misunderstood." Asserting that "Industry specifications state that cosmetic-grade talc must contain "no detectable fibrous, asbestos minerals," however, the Panel did not consider studies in which talc explicitly contained asbestos.

144. The CIR Panel reviewed a wide variety of products containing talc (e.g. body powders, makeup, hair shampoos and dyes, nail polish, shaving creams, deodorants, etc.), and determined that talc is safe in the present practices of use and concentration except for the application "to the skin when the epidermal barrier is missing or significantly disrupted." This recommendation was based on case-reports of granuloma formation in this setting. The Panel did not cite reports of granuloma formation and other inflammatory reactions in the peritoneal cavity when exposed to talc. Nor did the Panel consider the potential effects on the non-squamous cells of peritoneal surfaces, fallopian tubes, and ovaries or the frequent disruptions of the epithelial surface of the ovary with ovulation, ruptured cysts, infection, endometriosis and other physiologic and non-physiologic events.

145. The CIR review compares unfavorably in methodology, interpretation of the literature, and conclusions reached with the 2021 Health Canada assessment. A comparison of the two assessments is contained in Appendix 2.

[41] Despite stating that "[t]he articles . . . were sponsored by the Cosmetic Ingredient Review[]" which is "financially supported by the Personal Care Products Council[,]" the authors do not disclose that several of the authors are actually directly employed by PCPC (Fiume, Boyer, Anderson).

FDA has statutory authority to undertake its own evaluative activities for cosmetics, but it is underfunded, under-informed by the cosmetics industry, and often unwilling to take action even in response to citizen petitions.

146. Federal law allows individuals or companies to file petitions requesting that the FDA take or refrain from taking regulatory action – these are referred to as Citizen Petitions. The majority of Citizens Petitions filed with the FDA concern drugs and medical devices and it appears that only a small number of petitions concern cosmetics. Chen et al., Petitioning the FDA to Improve Pharmaceutical, Device and Public Health Safety by Ordinary Citizens: A Descriptive Analysis 11 PLoS ONE 137 (2016). 21 C.F.R. §§ 10.20, 10.25, and 10.30 describe the general administrative process for submitting a Citizen Petition to the FDA.

147. Most Citizen Petitions (over 80%) are filed by companies that have commercial interests in products regulated by the FDA. Of the relatively small number of Citizen Petitions filed by individuals and nonprofits, most are denied by the FDA (almost 90%).

148. 1 C.F.R. § 740.1 specifically allows citizens to file petitions seeking warning statements on cosmetics. ("The Commissioner of Food and Drugs[] . . . on behalf of any interested person who has submitted a petition, may publish a proposal to establish or amend, under subpart B of this part, a regulation prescribing a warning for a cosmetic.") Citizen Petitions may also request that the FDA declare a product or ingredient to be hazardous, or address almost any other regulatory concern.

149. It often takes the FDA years to formally respond to Citizen Petitions.

150. The FDA can respond to Citizen Petitions in one of four ways:

> (i) Approve the petition, in which case the Commissioner shall concurrently take appropriate action (e.g., publication of a Federal Register notice) implementing the approval;
> (ii) Deny the petition;
> (iii) Dismiss the petition if at any time the Commissioner determines that changes in law, facts, or circumstances since the date on which the petition was submitted have rendered the petition moot; or
> (iv) Provide a tentative response, indicating why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information. The tentative response may also indicate the likely ultimate agency response, and may specify when a final response may be furnished.
> 21 C.F.R. § 10.30(e)(2)(i)-(iv).

151. On November 17, 1994, Dr. Samuel Epstein of the Cancer Prevention Coalition submitted a Citizen Petition to the FDA asking that the FDA require the following warning on all talcum powder products: "Talcum powder causes cancer in laboratory animals. Frequent talc application in the female genital area increases risk of ovarian

cancer." [1994 CPC Citizen Petition] The petition cites epidemiology studies, human laboratory studies, and animal laboratory studies conducted from the 1960s to the 1990s.

152. On July 11, 1995, Dr. John Bailey, acting director of the FDA Office of Cosmetics and Colors, responded to the CPC but explained that the FDA has "not been able to reach a decision on your petition within the first 180 days of the filing of the petition because of the limited availability of resources and other agency priorities." [1995 FDA Response Letter] The FDA did not take any further action on this Citizen Petition until the late 2000s.

153. On May 13, 2008, Dr. Epstein of the CPC again submitted a Citizen Petition to the FDA asking that the FDA require the following warning on all talcum powder products: "Frequent application of talcum powder in the female genital area substantially increases the risk of ovarian cancer." [2008 CPC Citizen Petition] The 2008 Petition provides a detailed statement of grounds including some not contained in the 1994 Petition. The FDA did not take any further public action on this Citizen Petition until 2014.

154. On April 1, 2014, the FDA issued a letter denying the CPC's 1994 and 2008 Citizen Petitions. The letter includes the following statements:

> "A cogent biological mechanism by which talc might lead to ovarian cancer is lacking; exposure to talc does not account for all cases of ovarian cancer; and there was no scientific consensus on the proportion of ovarian cancer cases that may be caused by talc exposure." (at 4-5)
>
> "…the potential for talc particulates to migrate from the perineum and vagina to the peritoneal cavity is indisputable. It is, therefore, plausible that perineal talc (and other particulate) that reached the endometrial cavity, Fallopian Tubes, ovaries and peritoneum may elicit a foreign body reaction and inflammatory response that, in some exposed women, may progress to epithelial cancers." (at 5)
>
> "The best evidence for an association or causal relationship between genital talc exposure and ovarian cancer comes from epidemiologic data which show a statistically significant but modest increased risk of epithelial ovarian cancer, especially with serous histology, among women with a history of genital dusting with talcum powder. While the growing body of evidence to support a possible association between genital talc exposure and serous ovarian cancer is difficult to dismiss, the evidence is insufficient for FDA to require as definitive a warning as you are seeking."

155. The 2014 FDA denial letter is not well drafted. For example, the first part of the first statement above is inconsistent with the second statement, which posits a biological mechanism for talc carcinogenesis. The second and third parts of the first statement, focusing on the percentage of ovarian cancers that are talc-related, seem irrelevant to the

question of whether talc exposure causes ovarian cancer although it bears on the difficulty of quantifying risk.

156. The FDA denial letter is only denying the citizen request to issue its own specific warning language about the risk; it does not affect the manufacturer's independent legal obligation to warn of hazards, which is in the immediately preceding subsection of the regulation. Moreover, the FDA letter makes it clear that talc has not been proved safe and reinforces the conclusion that a "safety not determined" warning from the manufacturer is required. The FDA letter states that the science on baby powder and ovarian cancer is concerning and suggestive, which itself should constitute "new information" sufficient to trigger that warning.

157. The Regulation Modernization Act authorizes additional funding for FDA's cosmetics regulatory activities, offering hope that future citizen petitions and similar requests for action will generate prompt and protective agency responses under the expanded legal authority that now exists.

There are procedures established for the cosmetics industry to involve FDA in the self-regulation process, but Johnson & Johnson did not take advantage of these opportunities.

158. Prior to the very recent adoption of the Regulation Modernization Act, cosmetics regulation lacked statutory authority for mandatory reporting to regulators, as applies to drugs, because drugs are subject to FDA supervision of industry review for safety and effectiveness and cosmetics are not. FDA regulations do provide for a voluntary reporting system for registering facilities that manufacture cosmetics and for registering cosmetic ingredients. 21 C.F.R. Part 710 & Part 720. The FDA manages these voluntary reports through the Voluntary Cosmetic Registration Program (VCRP).[42] The Regulation Modernization Act phases out the VCRP and provides for a transition to a system of mandatory cosmetic product and facility registration, as well as mandatory reporting of adverse events.

159. There is no evidence that Johnson & Johnson registered all of the ingredients in their talcum powder products, and only registered ingredients listed on the product labels.

160. Companies can also voluntarily report adverse events related to cosmetics through the FDA Adverse Events Reporting System (FAERS) of the Center for Food Safety and Applied Nutrition's Adverse Event Reporting System (CAERS).

161. Johnson & Johnson has filed a small number of talcum powder-related adverse events reports, primarily (if not solely) in connection with being a named defendant in a legal complaint alleging physical injury to a consumer.

[42] https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program#about

162. At any time, Johnson & Johnson could have informed FDA of findings of asbestos, fibrous talc, and heavy metals in its talcum powder products.

Cosmetics regulation may be on the verge of significant reform and improvement because of unprevented harm to consumers, including talc-related injury, whether or not manufacturers cooperate. The Regulation Modernization Act, adopted in 2022, is an important step in this direction.

163. Litigation is not inconsistent with regulation. Personal injury litigation often provides important information to public policymakers, and it helps fill gaps in regulatory design and development. (Sage, Litigation and Regulation)

164. Cosmetics were incorporated into the food and drug regulatory regime during the 1930s because of reported harms to consumers.

165. The FTCA's pre-market approval requirements for drug safety and other expanded legal authorities, including for cosmetics, followed tragic events associated with the oral antibiotic elixir sulfanilimide. A medication that killed over 100 people could only be seized under prevailing law by FDA because it was dissolved in diethylene glycol, a deadly poison, rather than in alcohol as the term "elixir" implies, and was therefore misbranded.

166. Thalidomide birth injuries, prevented in the US by a dedicated FDA scientist, led to the enactment of effectiveness requirements for drug approval under the Kefauver-Harris Drug Amendments of 1962.

167. In recent years, there has been renewed interest by the FDA and Congress concerning the safety of cosmetic talcum powder products, and, more generally, in FDA's authority to regulate the cosmetic industry.

168. In 2016, the Senate Committee on Health, Education Labor and Pensions convened a hearing entitled "Exploring Current Practices in Cosmetic Development and Safety." Senator Diane Feinstein testified in support of a proposed law she co-sponsored with Senator Susan Collins: the Personal Care Product Safety Act. In her testimony, Senator Feinstein discussed the outdated laws governing cosmetic regulation and the need for updated laws to address the safety of cosmetic products.

169. Findings of asbestos contamination in one production lot of Johnson's Baby Powder and in cosmetics sold by retailers Claire's and Justice, were among the developments prompting a re-examination of cosmetics regulation by FDA leadership during the Trump administration. (Statement from Scott Gottlieb and Susan Mayne, March 5, 2019)

170. On March 12, 2019, the House Subcommittee of Economic and Consumer Policy of the Committee on Oversight & Reform held a hearing entitled "Examining the Public Health Risks of Carcinogens in Cosmetic Products." [Hearing Transcript] The hearing was held in response to reports that Johnson & Johnson knew its products contained

asbestos as well as recent testing results by FDA that showed asbestos in other cosmetic products. Two other related hearings follow later in 2019.

171. On December 4, 2019, the House Subcommittee of Health of the Committee on Energy and Commerce held a hearing entitled "Building Consumer Confidence by Empowering FDA to Improve Cosmetic Safety."

172. On December 10, 2019, the House Subcommittee of Economic and Consumer Policy of the Committee on Oversight & Reform held a hearing entitled "Examining Carcinogens in Talc and the Best Methods for Asbestos Detection."

173. Several bills were introduced or reintroduced during the 117th session of Congress (2021-2022) by Senators Feinstein, Collins, Hatch, Paul, and others. Provisions from these bills, as modified, ultimately were incorporated into the Regulation Modernization Act and passed and signed into law on December 29, 2022 as part of the omnibus Consolidated Appropriations Act, 2023.

D. Summary of Opinions

174. The cosmetic industry is self-regulated. Self-regulation depends on manufacturers selling only safe products containing safe ingredients, and on responsible disclosure of product information by manufacturers to consumers and voluntary reporting by manufacturers of such information to FDA. Federal food, drug, and cosmetics law enforces these obligations of product safety and information disclosure.

175. FDA does not supervise the self-regulation of cosmetics, whereas FDA closely supervises the self-regulation of drugs. Self-regulation of cosmetics is principally firm-based, with individual manufacturers committing to follow ethical and scientific practices, supported by industry norms and codes of conduct. Small modifications and improvements to this framework under the Regulation Modernization Act do not alter, and in fact reaffirm, this basic fact.

176. Johnson & Johnson did not establish or maintain the safety of its talcum powder products. Johnson & Johnson knew its products contained carcinogens, including asbestos, fibrous talc, and heavy metals. Johnson & Johnson did not perform studies on talcum powder that would address the concerns being raised in the medical and scientific literature. (O'Shaughnessy and Wille depositions)

177. Johnson & Johnson did not respond to or notify FDA of information that its talcum powder products and their ingredients may be associated with a health hazard.

178. Johnson & Johnson did not supply required warnings to consumers of health hazards associated with its talcum powder products.

179. Johnson & Johnson did not supply required warnings to consumers that the safety of its talcum powder products had not been determined.

180. Johnson & Johnson did not register its cosmetics accurately, did not inform FDA of positive testing results, and did not consistently report adverse events.

181. Johnson & Johnson marketed and sold a misbranded and adulterated product.

182. By relying on corporate and industry assessments that failed to frame or resolve key scientific questions, Johnson & Johnson assumed the safety of its products rather than substantiating it.

183. Johnson & Johnson did not inform consumers of risks or uncertainty about risks, and misled them with continued reassurances about safety and purity.

184. Johnson & Johnson did not follow its own safety standards or corporate pledge of legal compliance and ethical self-governance beyond what the marketplace had always accepted.

Appendix 1: Summary of scientific evidence relating to talcum powder and its association with ovarian cancer

1. In 1948, the Laboratories of Johnson & Johnson published an article describing the "incontrovertible evidence of the local irritant action" and the "potential hazards" from the use of talcum. (Eberl 1948). In a 1952 patent application for a starch derivative as a substitute for talc on surgical gloves, J&J cited the convincing evidence of strong inflammatory reactions, postoperative complications, and adhesions when talc was introduced into the peritoneal cavity.

2. In 1971, working at the Tenovus Institute for Cancer Research in Wales, electron microscopist, W.J. Henderson published his findings of talc particles de*eply embedded* in tissue from patients with ovarian tumors. This group had previously developed a technique for the study of foreign particles within tissues and had identified crocidolite asbestos within mesotheliomas. The authors raised the question of the association of talc with asbestos and the possibility of a relationship between the two minerals and carcinomatous changes in the ovary. (Henderson 1971).

3. Throughout the 1970s, there was a great deal of interest and research in the etiologies of gynecologic malignancies led by Dr. Donald Woodruff, widely considered the father of gynecologic pathology and Professor at Johns Hopkins. Dr. Woodruff began raising concern at lectures and in publications that there could be an environmental component in the pathogenesis of ovarian cancer, considering the unique nature of the female reproductive tract and ovarian tissue. He proposed that substances, specifically talc, could potentially reach the peritoneal cavity through the fallopian tube, produce proliferation, and contribute to the development of malignancy. (Parmley and Woodruff 1974; Woodruff 1979).

4. Dr. Woodruff, in "cruel and pessimistic words", described the prolonged debilitating and dehumanizing nature of death from ovarian cancer. He asked that more attention be paid to patients-at-risk and the agents introduced into the vaginal canal that may be transmitted to the peritoneal cavity with resultant mesothelial proliferation, and potential means of prevention, emphasizing that "AN OUNCE OF PREVENTION IS WORTH A POUND OF CURE." [caps Dr. Woodruff] (Woodruff 1979).

5. A series of articles and communications in the *Lancet* in the late 1970s and early 1980s discussed similar concerns regarding the use of a talc-dusted diaphragm or condom during intercourse. In a 1979 article titled Controversy, Longo and Young at the National Cancer Institute specifically cautioned the cosmetic industry:

> What is disturbing is that a consultant to the cosmetic industry feels that further research on the biological effects of talc 'merits little priority'…Talc is known to elicit potent inflammatory responses in man when found in the lungs, pleural cavity, and peritoneal cavity. To assume that its presence in diseased reproductive organs is benign on the basis of finding it in normal reproductive organs as well ignores its potential role as a co-carcinogen and is similar to arguments voiced against many agents which have already been proven carcinogenic. (Longo and Young 1979).

6. In 1995, the condom industry voluntarily chose to stop dusting condoms with talc due to ovarian cancer concerns. (PCPC MDL00062175)

7. The female reproductive tract has long been recognized as an open system and numerous substances have been shown to migrate or be transported to the peritoneal cavity and ovaries, including dead sperm or inanimate sperm particles, inert carbon particles, retrograde menstruation, particulate radioactive material, and starch particles. (Expert reports of Drs. Clarke-Pearson, Smith, and Wolf). These researchers consistently recognized the significance of these findings. For example, Venter and Iturralde, who studies particulate radioactive material, stated "Such migration could well explain the aetiological role of chemical substances in certain gynaecological diseases. . . If transit can take place so easily, it is probably the same for many chemical substances used for hygienic, cosmetic, or medicinal purposes, many of which may have potential carcinogenic or irritating properties." (Venter and Iturralde 1979) Sjosten et al., who studied corn starch stated, "any other potentially harmful substances that can migrate from the vagina should be avoided." (Sjosten 2004).

8. In 1982, Cramer with a multi-disciplinary team at Harvard that included epidemiology, pathology, and obstetrics and gynecology and sponsored by an NIH grant, published the first epidemiologic study showing an association between genital talcum powder use and ovarian cancer. This study was undertaken to address the possibility that ovarian cancer may be caused by certain minerals such as talc and asbestos that had been raised by other researchers. The authors described four elements in the argument linking talc and ovarian cancer: 1) the chemical relationship between talc and asbestos, 2) asbestos as a cause of pleural and peritoneal mesotheliomas, 3) the possible relationship between epithelial ovarian cancer and mesothelioma, and 4) the ability of talc to enter the pelvic cavity. Women who regularly used talcum powder as a dusting powder on the perineum and on sanitary napkins had a statistically significant adjusted relative risk of 3.28. Women with any perineal exposure had a relative risk of 1.93 (1.27-2.89). (Cramer 1982).

9. There have been approximately 28 case-control studies of talcum powder exposure and ovarian cancer, five studies reporting on 3 cohort studies, 7 meta-analyses of all epidemiologic studies up the published date, one pooled analysis of 8 case-control studies, and one pooled analysis of four cohort studies. (Expert Reports of Drs. McTiernan, Siemiatycki, and Smith-Bindman). The data from the meta-analyses show a consistent, statistically significant, increased risk of ovarian cancer with the regular genital use of talcum powder products. The pooled case-control analysis found similar statistically significant increased risks for epithelial ovarian cancer. (Terry 2013) A 2018 meta-analysis found a statistically significant 24%-39% increased risk of ovarian cancer. The authors concluded that the relationship with serous carcinoma was suggestive of a causal association. (Penninkilampi 2018) Although a recent pooled cohort analysis found a non-statistically significant 8% increased risk in women overall, a statistically significant 13% increased risk of ovarian cancer in women with patent genital tracts. (O'Brien 2021) The increased risk varies between 20-30% among studies and up to 50% when considering regular talcum powder use and the serous (most common) subtype of epithelial ovarian cancer. (Expert Reports of Drs. McTiernan, Siemiatycki, and Smith-Bindman)

10. Dr. William Longo and Dr. Mark Rigler have tested historical samples of Johnson's Baby Powder and Shower to Shower from the 1960s through the early 2000s and found that 98% of 56 samples contained fibrous talc and 68% of 65 samples contained asbestos.

(Longo and Rigler Expert Report 2019). In addition, I have seen numerous Johnson and Johnson testing results showing the presence of asbestos in their talcum powder products. (Exhibit 28, Deposition of John Hopkins, Ph.D., MDL No. 2378, 2018; Exhibit 47, Deposition of Julie Pier, MDL No. 2738, 2018).

11. In October, 2019, FDA found asbestos in a sample of Johnson's Baby Powder, resulting in Johnson & Johnson recalling 33,000 bottles from one lot. (BMJ 2019).

12. Talcum powder also contains nickel and chromium (Group 1 carcinogens), cobalt (Group 2B carcinogen) and fragrance chemicals, some of which are known to be inflammatory agents, toxins, and carcinogens. (Expert reports of Drs. Clarke-Pearson, Smith, and Wolf; Expert report of Dr. Crowley).

Appendix 2: Comparison of CIR and Health Canada Assessments

1. *Safety*:
   - Health Canada: The available data are indicative of a causal effect between the perineal exposure to talc and ovarian cancer.
   - CIR: Talc is safe in the present practices of use and concentration.
2. *Epidemiologic Studies*:
   - Health Canada: There is a high degree of consistency in the epidemiological studies across several decades conducted in different parts of the world. Conclusion is based on 1) the pooled ORs from available meta-analyses range from 1.22 to 1.35; 2) these results are statistically significant, with narrow confidence intervals; 3) case-control designs are well suited to study perineal talc exposure and ovarian cancer and the available cohort studies are not without limitations; and 4) there is confidence in the robustness of the available database for use in characterizing ovarian cancer risk attributed to talc exposure.
   - CIR: Numerous epidemiological studies do not support a causative relationship between the cosmetic use of talc in the perineal area and ovarian cancer. Conclusion is based on 1) lack of consistent statistically significant positive associations across studies; 2) uniformly small RR estimates in studies reporting positive associations; and 3) failure to rule out plausible alternative explanations of the statistically significant results, including biases, confounding risk factors, and exposure misclassifications.
3. *Migration of particles:*
   - Health Canada: The available animal and human studies clearly indicate that particles, including talc, may transfer from the vagina to the fallopian tubes and ovaries following perineal application. (p. 33) Migration or retrograde movement of talc particles from the vagina to the ovaries has been identified as a plausible explanation of the presence of talc particles in the upper reproductive tract. (Henderson et al. 1986; Heller et al. 1996; Cramer et al. 2007). (18) Evidence considered: FDA 2014 “indisputable”, Schildkraut 2016, Wehner 1977b, Zervomanolakis 2007, Peters 2006, Henderson 1986, Phillips 1978, Wehner), Edelstam 1997, Sjosten 2004, Egli & Newton 1961, DeBoer 1972, Kunz 1996, Kissler 2004, McDonald 2019a, Johnson 2020.
   - CIR: Causation would depend on migration of talc from the perineum and ovaries. Persuasive evidence that talc can migrate from the perineum to the ovaries is absent. This conclusion is based on 1) there is no conclusive explanation for the presence of talc in the ovaries reported in some studies and 2) there is no known physiological mechanism by which talc can plausibly migrate from the perineum to the ovaries. For this conclusion, CIR relies heavily on non-human studies, appears to discount the conclusions of the authors of the relevant studies, and ignores the extensive literature relating to the uterine peristaltic pump and other physiologic processes in the female reproductive tract.
4. *Talc is inflammatory in tissue:*
   - Health Canada: An inflammatory response associated with talc has been clearly demonstrated in human lung tissue. While animal models are generally inadequate to assess ovarian cancer risk, the available animal studies (noting

inflammatory response to talc and the ability of talc particles to migrate up the reproductive tract) support biological plausibility and results were consistent with a possible human mode of action for cancer development.

- CIR: The inflammatory properties of talc are discussed in humans and animals in multiple places in the CIR assessment; However, this fact is discounted or ignored when assessing the implications for a relationship between talc exposure and ovarian cancer. For example, the Panel states that "talc is not allowed for use on the surface of medical gloves" and should not be applied to the skin when the epidermal barrier is missing or significantly disrupted - but does not discuss why this is important.

5. *Inflammation and ovarian cancer:*
   - Health Canada: There is support for an association between inflammation and an increased risk of ovarian cancer.
6. CIR: Although the Panel admits that some researchers have suggested that talc in the ovaries could cause cancer, indirectly, through a talc-induced inflammatory response, analogous to the action of asbestos fibers in the lungs, it concludes that a plausible biologic mechanism is absent. The CIR bases this conclusion on the statement that pelvic inflammatory diseases, such as endometriosis, peritonitis, and tubo-ovarian abscess formation, have not been found to be associated with increased risks of ovarian cancer, and, in addition, anti-inflammatory drug use did not reduce ovarian cancer risk estimates in several studies. These statements are misleading and inaccurate. (Expert Reports of Drs. Clarke-Pearson, Wolf, and Smith citing the peer-reviewed literature on risk factors associated with ovarian cancer)

Appendix 3: Relevant cosmetic laws and regulations (prior to the Modernization of Cosmetics Regulation Act of 2022)

Law	Title	Text	Enactment
21 U.S.C. § 321(i)	Definitions; generally	(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.	Act June 25, **1938**, ch 675, Ch. II, § 201, 52 Stat. 1040; July 22, 1954, ch. 559, § 1, 68 Stat. 511; Sept. 6, 1958, P. L. 85-929, § 2, 72 Stat. 1784; July 12, 1960, P. L. 86-618, Title I, § 101, 74 Stat. 397; Oct. 10, 1962, P. L. 87-781, Title I, Part A, § 102(a), Title III, § 307(a), 76 Stat. 781, 796; July 15, 1965, P. L. 89-74, §§ 3(a), 9(b), 79 Stat. 227, 234; July 13, 1968, P. L. 90-399, § 102, 82 Stat. 351; Oct. 24, 1968, P. L. 90-639, §§ 1, 4(a), 82 Stat. 1361, 1362; Oct. 27, 1970, P. L. 91-513, Title

			II, Part G, § 701(a), (g), 84 Stat. 1281, 1282; Oct. 21, 1972, P. L. 92-516, § 3(3), 86 Stat. 998; April 22, 1976, P. L. 94-278, Title V, § 502(a)(2)(A), 90 Stat. 411; May 28, 1976, P. L. 94-295, § 3(a)(1)(A), (2), 90 Stat. 575; Nov. 23, 1977, P. L. 95-203, § 4(b)(3), 91 Stat. 1453; Sept. 26, 1980, P. L. 96-359, § 3, 94 Stat. 1193; Nov. 16, 1988, P. L. 100-670, Title I, § 107(a)(1), 102 Stat. 3984; Nov. 8, 1990, P. L. 101-535, § 5(b), 104 Stat. 2362; Nov. 28, 1990, P. L. 101-629, § 16(b), 104 Stat. 4526; May 13, 1992, P. L.

			102-282, § 6, 106 Stat. 161; June 16, 1992, P. L. 102-300, § 6(a), (b), 106 Stat. 240; Oct. 29, 1992, P. L. 102-571, Title I, § 107(1), 106 Stat. 4499; Aug. 13, 1993, P. L. 103-80, §§ 3(b), (dd)(1), 4(b), 107 Stat. 775, 779; Oct. 25, 1994, P. L. 103-417, §§ 3(a), (b), 10(a), 108 Stat. 4327, 4332; Aug. 3, 1996, P. L. 104-170, Title IV, § 402, 110 Stat. 1513; Nov. 21, 1997, P. L. 105-115, Title I, Subtitle B, §§ 121(a), 125(b)(2), (e) 111 Stat. 2320, 2325, 2327; Oct. 30, 1998, P. L. 105-324, § 2(a), (c), 112 Stat. 3035, 3037;

			Jan. 4, 2002, P. L. 107-109, § 5(b)(1), 115 Stat. 1413; Oct. 26, 2002, P. L. 107-250, Title III, § 302(d), 116 Stat. 1619; Aug. 2, 2004, P. L. 108-282, Title I, §§ 102(b)(1), (5)(A), (B), 203(c)(1), 118 Stat. 892, 902, 908; Sept. 27, 2007, P. L. 110-85, Title X, § 1005(c), 121 Stat. 968; June 22, 2009, P. L. 111-31, Div A, Title I, § 101(a), 123 Stat. 1783; Dec. 13, 2016, P. L. 114-255, Div A, Subtitle F, § 3060(d), 130 Stat. 1133; Jan. 5, 2021, P.L. 116-304, § 2(b), 134 Stat. 4916.
21 U.S.C. § 361	Adulterated cosmetics	A cosmetic shall be deemed to be adulterated—(a) If it bears or contains any poisonous or deleterious substance which may render it	Act June 25, **1938**, ch 675, Ch. VI,

		injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual, except that this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.", and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes. (b) If it consists in whole or in part of any filthy, putrid, or decomposed substance. (c) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. (d) If its container is composed in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health. (e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 721(a) [21 USCS § 379e(a)].	§ 601, 52 Stat. 1054; July 12, 1960, P. L. 86-618, Title I, § 102(c)(1), 74 Stat. 398; Oct. 29, 1992, P. L. 102-571, Title I, § 107(11), 106 Stat. 4499; Aug. 13, 1993, P. L. 103-80, § 3(x), 107 Stat. 778.
21 U.S.C. § 362	Misbranded cosmetics	A cosmetic shall be deemed to be misbranded— (a) If its labeling is false or misleading in any particular. (b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary. (c) If any word, statement, or other information required by or under authority of this Act to	Act June 25, **1938**, ch 675, Ch. VI, § 602, 52 Stat. 1054; July 12, 1960, P. L. 86-618, Title I, § 102(c)(2), 74 Stat. 398; Dec. 30, 1970, P. L. 91-601, § 6 [7](f), 84

		appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. (d) If its container is so made, formed, or filled as to be misleading. (e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 721 [21 USCS § 379e]. This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 601(a) [21 USCS § 361(a)]). (f) If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970 [15 USCS § 1472 or 1473].	Stat. 1673; Aug. 13, 1981, P. L. 97-35, Title XII, Subtitle A, § 1205(c), 95 Stat. 716; Oct. 29, 1992, P. L. 102-571, Title I, § 107(12), 106 Stat. 4499.
21 C.F.R. § 700.3	Definitions	(b) The term cosmetic product means a finished cosmetic the manufacture of which has been completed. Any cosmetic product which is also a drug or device or component thereof is also subject to the requirements of Chapter V of the act.	[39 FR 10054, March 15, **1974**, as amended at 46 FR 38073, July 24, 1981]
21 C.F.R. § 700.3	“	(d) The term fragrance means any natural or synthetic substance or substances used solely to impart an odor to a cosmetic product.	“
21 C.F.R. § 700.3	“	(e) The term ingredient means any single chemical entity or mixture used as a component in the manufacture of a cosmetic product.	“
21 C.F.R. § 700.3	“	(f) The term proprietary ingredient means any cosmetic product ingredient whose name, composition, or manufacturing process is protected from competition by secrecy, patent, or copyright.	“
21 C.F.R. §	“	(h) The term cosmetic raw material means any	“

700.3		ingredient, including an ingredient that is a mixture, which is used in the manufacture of a cosmetic product for commercial distribution and is supplied to a cosmetic product manufacturer, packer, or distributor by a cosmetic raw material manufacturer or supplier.	
21 C.F.R. § 700.3	"	(j) Establishment means a place of business where cosmetic products are manufactured or packaged.	"
21 C.F.R. § 700.3	"	(k) The term manufacture of a cosmetic product means the making of any cosmetic product by chemical, physical, biological, or other procedures, including manipulation, sampling, testing, or control procedures applied to the product.	"
21 C.F.R. § 700.3	"	(l) The term packaging of a cosmetic product means filling or labeling the product container, including changing the immediate container or label (but excluding changing other labeling) at any point in the distribution of the cosmetic product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer.	"
21 C.F.R. § 701.1	Misbranding	(a) Among representations in labeling of a cosmetic which render such cosmetic misbranded is a false or misleading representation with respect to another cosmetic or a food, drug, or device. (b) The labeling of a cosmetic which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such cosmetic in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.	[39 FR 10056, March 15, **1974**]
21 C.F.R. § 701.3(a)	Designation of Ingredients	(a) The label on each package of a cosmetic shall bear a declaration of the name of each ingredient in descending order of predominance, except that fragrance or flavor may be listed as fragrance or flavor. An ingredient which is both fragrance and flavor shall be designated by each of the functions it performs unless such ingredient is identified by name. No ingredient may be designated as fragrance or flavor unless	

		it is within the meaning of such term as commonly understood by consumers.	
21 C.F.R. § 740.1(a)	Establishment of warning statements	(a) The label of a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product.	[40 FR 8917, March 3, **1975**, as amended at 42 FR 15676, March 22, 1977]
21 C.F.R. § 740.1 (b)	"	(b) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish or amend, under subpart B of this part, a regulation prescribing a warning for a cosmetic. Any such petition shall include an adequate factual basis to support the petition, shall be in the form set forth in part 10 of this chapter, and will be published for comment if it contains reasonable grounds for the proposed regulation.	"
21 C.F.R. § 740.10 (a)	Labeling of cosmetic products for which adequate substantiation of safety has not been obtained	(a) Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel: Warning — The safety of this product has not been determined.	[40 FR 8917, March 3, **1975**]
21 C.F.R. § 740.10 (b)	"	(b) An ingredient or product having a history of use in or as a cosmetic may at any time have its safety brought into question by new information that in itself is not conclusive. The warning required by paragraph (a) of this section is not required for such an ingredient or product if: (1) The safety of the ingredient or product had been adequately substantiated prior to development of the new information; (2) The new information does not demonstrate a hazard to human health; and (3) Adequate studies are being conducted to determine expeditiously the safety of the ingredient or product.	"

		(c) Paragraph (b) of this section does not constitute an exemption to the adulteration provisions of the Act or to any other requirement in the Act or this chapter.	
21 C.F.R. § 10.25	Initiation of administrative proceedings	An administrative proceeding may be initiated in the following three ways: (a) An interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action. A petition must be either: . . . (2) in the form for a citizen petition in § 10.30. (b) The Commissioner may initiate a proceeding to issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action. . . . . (c) The Commissioner will institute a proceeding to determine whether to issue, amend, or revoke a regulation or order, or take or refrain from taking any other form of administrative action whenever any court, on its own initiative, holds in abeyance or refers any matter to the agency for an administrative determination and the Commissioner concludes that an administrative determination is feasible within agency priorities and resources.	[44 FR 22323, Apr. 13, **1979**, as amended at 54 FR 9034, Mar. 3, 1989]
21 C.F.R. § 10.30	Citizen petition	(a) This section applies to any petition submitted by a person (including a person who is not a citizen of the United States) except to the extent that other sections of this chapter apply different requirements to a particular matter. . . . (1) The Commissioner shall, in accordance with paragraph (e)(2), rule upon each petition filed under paragraph (c) of this section, taking into consideration (i) available agency resources for the category of subject matter, (ii) the priority assigned to the petition considering both the category of subject matter involved and the overall work of the agency, and (iii) time requirements established by statute. (2) Except as provided in paragraphs (e)(4) and (5) of this section, the Commissioner shall furnish a response to each petitioner within 180	[44 FR 22323, Apr. 13, **1979**, as amended at 46 FR 8455, Jan. 27, 1981; 50 16656, Apr. 26, 1985; 54 FR 9034, Mar. 3, 1989; 57 FR 17980, Apr. 28, 1992; 59 FR 14364, Mar. 28, 1994; 62 FR 40570, 40592, July 29, 1997; 66

		days of receipt of the petition. The response will either: (i) Approve the petition, in which case the Commissioner shall concurrently take appropriate action (e.g., publication of a FEDERAL REGISTER notice) implementing the approval; (ii) Deny the petition; (iii) Dismiss the petition if at any time the Commissioner determines that changes in law, facts, or circumstances since the date on which the petition was submitted have rendered the petition moot; or (iv) Provide a tentative response, indicating why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information. The tentative response may also indicate the likely ultimate agency response, and may specify when a final response may be furnished. . . .	FR 6465, 6467, Jan. 22, 2001; 66 FR 12848, Mar. 1, 2001; 78 FR 76748, 76749, Dec. 19, 2013; 81 FR 78500, 78505, Nov. 8, 2016]

Exhibit A

WILLIAM M. SAGE, MD, JD

Texas A&M University
1515 Commerce Street
Fort Worth, Texas 76102

william.sage@tamu.edu

Employment

Texas A&M University (2022-)	Professor of Law; Professor of Medicine (Department of Translational Medical Science); Professor (by courtesy) of Government and Public Service; Assistant Vice President, Health Science Center; founding director, institute for health care access (under development)
The University of Texas at Austin Austin, TX (2006-2022)	James R. Dougherty Chair, School of Law and Professor of Surgery and Perioperative Care, Dell Medical School; Vice Provost for Health Affairs (2006-2013)
Columbia University New York, NY (1995-2006)	Professor of Law (2001-2006); Associate Professor of Law (1995-2001)
The White House Washington, DC (1993)	Cluster Leader, Health Care Working Group (President's Task Force on Health Care Reform)
O'Melveny & Myers Los Angeles, CA (1990-93; 1993-95)	Associate, Corporations Department (public finance, securities, mergers and acquisitions)
The Johns Hopkins Hospital Baltimore, MD (1989-90)	Resident in Anesthesiology and Critical Care Medicine
Mercy Hospital and Medical Center San Diego, CA (1988-89)	Intern (Transitional)
Davis Polk & Wardwell New York, NY (1987)	Summer Associate

Academic Degrees

Harvard College (1978-82)	AB magna cum laude in biochemical sciences (Phi Beta Kappa; John Harvard Scholar)
Stanford University (1982-88)	MD with research honors in anesthesia and critical care medicine (Alumni Scholar) JD with distinction (Order of the Coif; note editor, *Stanford Law Review*)
Université Paris Descartes (2011)	Docteur honoris causa

Licensure

Medicine: California (1989, inactive); New York (1996, inactive); Texas (2008)
Law: California (1990, inactive); District of Columbia (1991, inactive)

Professional Honors

Elected Member, National Academy of Medicine
Elected Member, American Law Institute
Elected Fellow, The Hastings Center on bioethics
Elected Fellow, New York Academy of Medicine
Elected Member, The Academy of Medicine, Engineering and Science of Texas
Permanent Member, Hagler Institute for Advanced Study, Texas A&M University
Honorary Member, Delta Omega National Public Health Honor Society (Alpha Tau Chapter)
Honorary Fellow, American College of Legal Medicine

Teaching and Service

Current/Recent Courses
Health Law and Policy (interdisciplinary with law, medicine, public affairs, and business)
Legislation, Regulation, and Public Policy (core "leg-reg" class)
Professional Ethics: Comparing Law and Medicine (core legal ethics class)
Health Justice and the Medical-Legal Partnership (interdisciplinary with law, medicine, and social work)
Advanced Health Law: Competition, Regulation, and Professionalism
Developing Outstanding Clinical Skills (DOCS) (Dell Medical School)
Foundations for Leadership Practice (Dell Medical School)
Applying Leadership Skills (Dell Medical School)

Past Teaching:
Problems in Health Policy and How to Solve Them (UT Plan II Liberal Arts honors program)
Advanced Health Policy (UT interdisciplinary with law, nursing, pharmacy, and social work)
Health Policy (Emory University interdisciplinary)
Health Law (Columbia Law School, Harvard Law School, Yale Law School, Duke Law School)
Antitrust (Columbia Law School)
Professional Responsibility (Emory Law School, Harvard Law School, Duke Law School)
Foundations of the Regulatory State (Columbia University School of Law)
Professions and Professionals (UT Law and Medicine, Columbia University School of Law and College of Physicians & Surgeons; Yale Law School and Yale School of Medicine)

Visiting Professorships and Other Teaching Positions
George Washington University School of Law (Fall 2021)
New York University School of Law (2019-2020)
and Dept. of Population Health, School of Medicine (2019-)
Emory Law School (Spring 2018)
Yale Law School (Spring 2013)
Harvard Law School (Fall 2007)
University of Texas School of Law (2005-2006)
Duke University School of Law (Spring 2001)
Université Paris Descartes (professeur invite, faculté de droit, 2013-2017)
University of Minnesota Law School/School of Public Health (visiting scholar, Fall 2003)

Tokyo University Law Faculty (Columbia Law School exchange program, October 1997)
Leyden-Amsterdam-Columbia Summer Program in American Law (July 1997)
USC School of Medicine (adjunct faculty, 1991-95)
UCLA School of Medicine (adjunct faculty, 1991-92)

University Service
Innovation and Leadership Curriculum Committee, Dell Medical School (2015-18)
Task Force on Student Life (UT Law School) (chair 2014-16)
Commencement speaker, University of Texas at Austin School of Nursing (December 2011)
Commencement speaker, University of Texas College of Pharmacy (May 2011)
Robert W. Hamilton Book Awards (committee 2012; chair 2014) (UT Austin)
Transformation in Medical Education (TIME) Steering Committee (UT System)
Institute for Cancer Care Excellence special advisory group (MD Anderson Cancer Center)
Committee on Sustainability (UT Austin)
Subcommittee on Patient Safety Disclosure (UT System)
IRB Task Force (UT System)
Dean search committees (schools of nursing, pharmacy, social work) (UT Austin)

Advisory Boards and Community Service
Editorial Board, *Health Affairs* (1998-)
Member, Healthcare System and Value Research (HSVR) study section, Agency for Healthcare Research and Quality (AHRQ) (2021-)
Advisor, American Law Institute, Restatement (Third) on Torts: Medical Malpractice (2020-)
National Advisory Council, National Center on Medical-Legal Partnership (2019-)
Board on Health Care Services, National Academies of Science, Engineering, and Medicine (2017-23)
Children's Optimal Health (nonprofit GIS mapping) (chair, 2015-19; vice chair, 2008-15)
ChangeLab Solutions (Public Health Law & Policy) Board of Directors (2009-17)
Code Red Task Force on the Uninsured in Texas (2007-15)
Conseil scientifique, Institut Droit et Sante, Universite de Paris V (2007-16)
Partners in Austin Transforming Health (PATH) (steering committee, 2015-2022)
Policy Committee, Collaborative on Accountability and Improvement (co-chair, 2016-19)
Program Committee, Health Professions Interest Group, National Academy of Medicine (2016-20)
Fellows Council, The Hastings Center (2007-12)
Nat'l Advisory Committee, RWJF National Policy and Legal Advisory Network (2008-17)
Editorial Board, Agency for Healthcare Research and Quality WebM&M/PSNet (2009-14)
Steering Committee, Clinical Education Center at University Medical Center/Brackenridge (2007-10)

Special Advisory Service
Peer Reviewer, National Academies of Science, Engineering, and Medicine Report on *Decadal Survey of Behavioral and Social Science Research on Alzheimer's Disease and Related Dementias* (2021)
Observer, Uniform Law Commission Drafting Committee on Updating the Uniform Determination of Death Act (2021-)
Observer, Uniform Law Commission Study Committee on Updating the Uniform Determination of Death Act (2020-21)
Peer Reviewer, American Law Institute, Restatement of the Law Third, Torts: Concluding Provisions (2020)
Member, National Academy of Medicine, Committee on the Future of Nursing 2020-2030 (2019-21)
Monitor, National Academies of Science, Engineering, and Medicine Report on *Regulating Medicines in a Globalized World* (2019)

Peer Reviewer, National Academies of Science, Engineering, and Medicine Report on *Systems Approaches to Improve Patient Care by Supporting Clinician Well-Being* (2019)
Peer Reviewer, National Academies of Science, Engineering, and Medicine Report on *Making Medicine Affordable: A National Imperative* (2017)
Consultant, Competition Commission of South Africa, Private Health Care Sector Market Inquiry (2015-17)
Peer reviewer, Harvard University Report on *Protecting and Promoting the Health of NFL Players: Legal and Ethical Analysis and Recommendations* (2015)
Peer reviewer, IOM Report on *The Future of Nursing: Five Years Later* (2015)
AHRQ Special Review Panel for R21 Grants on Patient Safety and Medical Liability (2010)
AHRQ Advisory Council Subcommittee on Patient Safety and Medical Liability (2009-2010)
Texas Health Services Authority, HIE Governance and Finance Workgroup (2010)
JCAHO Tort Resolution and Injury Prevention Roundtable (2004-2005)
Institute of Medicine, Committee on Rapid Advance Demonstration Projects (2002)
The Hastings Center, Working Group on Conflicts of Interest in Research (2002-2003)
The Hastings Center, Working Group on Ethical Issues in Patient Safety (2001-2002)
New York State Dept. of Health Workgroup on IRB Guidelines (1997-1998)

Grants

"A Right to Be Counted: Enhancing Syndromic Surveillance Capabilities for Vulnerable Gulf Communities" (Principal investigator: National Academies Gulf Research Program/Robert Wood Johnson Foundation NAS Grant Number: SCON-10000856, 2023-2025; $1.5 million)

"Health Reform, Competition Policy, and Emerging Health Care Markets" (Principal investigator: Commonwealth Fund, 2013)

"The Texas Disclosure and Compensation Study: Best Practices for Improving Safety" (Co-investigator: Agency for Healthcare Research and Quality, 2010-2014; $1.3 million)

"Medicare-Led Malpractice Reform" (Principal investigator: Commonwealth Fund, 2005-2007)

"A Mediation Skills Approach to Disclosing Medical Error" (Co-investigator: Agency for Healthcare Research and Quality conference grant, 2004)

"Project on Medical Liability in Pennsylvania" (Principal investigator: The Pew Charitable Trusts, 2002-2005; $3.5 million)

"Competing on Quality of Care" (Investigator Award in Health Policy Research: Robert Wood Johnson Foundation, 1998-2001)

Publications

Books

Bernard S. Black, David A. Hyman, Myungho Paik, William M. Sage, and Charles Silver. *Medical Malpractice Litigation: How It Works, Why Tort Reform Hasn't Helped.* Washington, DC: Cato Institute 2021.

Oxford Handbook of U.S. Health Law (I. Glenn Cohen, Allison Hoffman, and William M. Sage, eds.). New York: Oxford University Press 2016.

Medical Malpractice and the U.S. Health Care System (William M. Sage and Rogan Kersh, eds.). New York: Cambridge University Press 2006.

Uncertain Times: Kenneth Arrow and the Changing Economics of Health Care (Peter J. Hammer, Deborah Haas-Wilson, Mark A. Peterson, and William M. Sage, eds.). Durham, NC: Duke University Press 2003.

Book Chapters

Sage WM. Private Law as Health Law: What It Means, Why It Matters, in *Health Law as Private Law* (I. Glenn Cohen, Wendy Netter Epstein, Christopher Robertson, Carmel Shachar eds.). Cambridge University Press (forthcoming 2024).

Sage WM, Tiase VL. Risk, Responsibility, Resilience, Respect: COVID-19 and the Protection of Health Care Workers, in *COVID-19 and the Law: Disruption, Impact, and Legacy* (I. Glenn Cohen, Abbe R. Gluck, Katherine L. Kraschel, Carmel Shachar eds.). Oxford University Press (forthcoming).

Sage WM. Appendix E: The Future of Nursing 2020-2030: Meeting America Where We Are: Supplemental Statement of William M. Sage, M.D., J.D., in *The Future of Nursing 2020-2030: Charting a Path to Achieve Health Equity*. (Mary Wakefield, David R. Williams, Suzanne Le Menestrel, and Jennifer L. Flaubert, eds.). The National Academies Press 2021 (available at https://www.nap.edu/read/25982/chapter/18).

Santuari A, Sage W. Paradigms of Healthcare Systems, Law, and Regulation: A Transatlantic Conversation, in *Oxford Handbook of Comparative Healthcare Law* (Tamara Hervey & David Orentlicher, eds.). New York: Oxford University Press 2021: [1-51] (DOI:10.1093/oxfordhb/9780190846756.013.47).

Sage WM, Cohen IG, Hoffman AK. Health Care Law and Ethics, in *Health Systems Science* (2nd edition; Susan Skochelak ed.) Philadelphia: Elsevier Health Sciences, 2020: 220-242.

Sage WM. Explaining America's Spendthrift Health Care System: The Enduring Effects of Public Regulation on Private Competition, in *The Law and Policy of Healthcare Financing* (Wolf Sauter, Jos Boertjens, Johan van Manen, and Misja Mikkers, eds.) Cheltenham, UK: Edward Elgar Publishing, 2019: 17-36.

Etchegaray JM, Gallagher TH, Bell SK, Sage WM, Thomas EJ. Error Disclosure Training and Organizational Culture, in *Advances in Patient Safety and Medical Liability*. (James Battles J, Irim Azam, Mary Grady, and Kathryn Reback, eds.). Rockville, MD: Agency for Healthcare Research and Quality 2017 (AHRQ Pub. No. 17-0017, Aug. 2017): 65-78.

Sage WM, Ottosen MJ, Coopwood TB. A Quiet Revolution: Communicating and Resolving Patient Harm, in *Surgical Patient Care: Improving Safety, Quality, and Value* (Juan A. Sanchez, Paul Barach, Julie K. Johnson, and Jeffrey P. Jacobs, eds.). New York: Springer Science+Business Media 2017: 649-664.

Sage WM. Antitrust Law and Competition Policy in U.S. Health Care, in *Oxford Handbook of U.S. Health Law* (I. Glenn Cohen, Allison Hoffman, and William M. Sage, eds.). New York: Oxford University Press 2016: 606-636.

Sage WM. Relating Health Law to Health Policy: A Frictional Account, in *Oxford Handbook of U.S. Health Law* (I. Glenn Cohen, Allison Hoffman, and William M. Sage, eds.). New York: Oxford University Press 2016: 3-28.

Sage WM. Some Principles Require Principals: Why Banning "Conflicts of Interest" Won't Solve Incentive Problems in Biomedical Research, in *Trust and Integrity in Biomedical Research: The Case of Financial Conflicts of Interest* (Thomas H. Murray and Josephine Johnston, eds.). Baltimore, MD: The Johns Hopkins University Press 2010: 188-213.

Sage WM and Leibenluft RF. Overcoming Barriers to Collaboration and Alignment: Legal and Regulatory Issues, in *Physician-Hospital Integration* (Francis J. Crosson and Laura Tollen, eds.). New York: Jossey-Bass 2010: 110-140.

Sage WM. Solidarity, in *Connecting American Values with American Health Care Reform* (Thomas H. Murray and Mary Crowley, eds.). Garrison, NY: The Hastings Center 2009: 10-12.

Sage WM. Paying Research Subjects: The U.S. Example, in *Essais cliniques, quels risques?* (Anne Laude and Didier Tabuteau, eds.). Paris: Presses Universitaires de France 2007: 137-152.

Sage WM and Kinney ED. Medicare-Led Malpractice Reform, in *Medical Malpractice and the U.S. Health Care System* (William M. Sage and Rogan Kersh, eds.). New York: Cambridge University Press 2006: 318-349.

Sage WM. Malpractice Reform as a Health Policy Problem, in *Medical Malpractice and the U.S. Health Care System* (William M. Sage and Rogan Kersh, eds.). New York: Cambridge University Press 2006: 30-42.

Sage WM and Kersh RT. Introduction, in *Medical Malpractice and the U.S. Health Care System* (William M. Sage and Rogan Kersh, eds.). New York: Cambridge University Press 2006: 1-8.

Sage WM. New Directions in Medical Liability Reform, in *Malpractice and Medical Practice Handbook* (Richard Anderson, ed.). Totowa, New Jersey: Humana Press 2005: 247-278.

Sage WM. Reputation, Malpractice Liability, and Medical Error, in *Accountability: Patient Safety and Policy Reform* (Virginia A. Sharpe, ed.). Washington, DC: Georgetown University Press 2004: 159-183.

Sage WM. Panel Presentation on Education in Professional Values and Rules, in Record of Proceedings, Convocation on the Face of the Profession II: The First Seven Years of Practice. *Journal of the New York State Judicial Institute on Professionalism in the Law* 2003; 3(1): 38-44.

Sage WM. Understanding the First Malpractice Crisis of the 21st Century, in *2003 Health Law Handbook* (Alice G. Gosfield, ed.). St. Paul, Minnesota: West Group: 2003; 1-32.

Institute of Medicine. Fostering Rapid Advances in Health Care: Learning from System Demonstrations (Janet M. Corrigan, Ann Greiner, and Shari M. Erickson, eds.). Washington, DC: National Academies Press: 2002 (committee member and chapter author).

Hammer PJ and Sage WM. Health Care Quality and Antitrust Law: Lessons from the Cases, in *2002 Health Law Handbook* (Alice G. Gosfield, ed.). St. Paul, Minnesota: West Group: 2002; 549-608.

Warren SH and Sage WM. Feasting in a Flak Jacket: Bankruptcy Risks and Opportunities for Solvent Health Care Organizations, in *1998 Health Law Handbook* (Alice G. Gosfield, ed.). Deerfield, Illinois: Clark Boardman Callaghan; 1998; 443-468.

Sage WM and Aiken LH. Regulating Interdisciplinary Practice, in *Regulation of the Healthcare Professions* (Timothy S. Jost, ed.). Chicago: Health Administration Press; 1997; 71-101.

Sage WM. Mandatory Consumer Disclosure in Managed Care: Lessons from the Securities Industry, in *Achieving Quality in Managed Care: The Role of Law* (ABA Health Law Section Monograph 5, June 1997). Chicago: American Bar Association; 1997; 99-121.

Sage WM and Anderson D. Health Care Disclosure Requirements, in *1997 Health Law Handbook* (Alice G. Gosfield, ed.). Deerfield, Illinois: Clark Boardman Callaghan; 1997; 185-205.

Sage WM and Scott CD. Community Health Information Networks, in *1996 Health Law Handbook* (Alice G. Gosfield, ed.). Deerfield, Illinois: Clark Boardman Callaghan; 1996; 403-436.

Sage WM. Courts, Coverage and Managed Care: Do We Really Want an Adversarial Health Care System?, in *Medical Necessity: A Symposium on Policy Issues, Implementation Challenges and Tough Choices*. Washington, D.C.: Agency For Health Care Policy and Research/National Institute For Health Care Management; 1995: 63-73.

Warren SH and Sage WM. With Friends Like These...: Protecting Participants in Integrated Systems from Bankruptcy and Insolvency Risks, in *1995 Health Law Handbook* (Alice G. Gosfield, ed.). Deerfield, Illinois: Clark Boardman Callaghan; 1995; 115-151.

Articles (*Refereed/peer reviewed publications)

*Sage WM, Warren KD. Swimming Upstream Together: How to Align MLP Services with U.S. Healthcare Delivery. *Journal of Law, Medicine, and Ethics* 2023 (forthcoming)

Cortez N, Sage WM. The Disembodied First Amendment. *Washington University Law Review* 2022; 100(3): 707-764 (published in 2023).

*Sage WM, Yang YT. Reducing "COVID Misinformation" While Preserving Free Speech. *JAMA* 2022 (published online Mar. 31, 2022; https://jamanetwork.com/journals/jama/fullarticle/2790859).

Sage WM. What the Pandemic Taught Us: The Health Care System We Have Is Not the System We Hoped We Had, *Ohio State Law Journal* 2021; 82(5): 857-868 (invited commentary).

*Sage WM. Adding Principle to Pragmatism: The Transformative Potential of "Medicare-for-All." *Yale Journal of Health Policy, Law, and Ethics* 2021; 20(1): 1-64.

*Sage WM, Westmoreland TM. Following the Money: The ACA's Fiscal-Political Economy and Lessons for Future Health Care Reform, *Journal of Law, Medicine & Ethics* 2020; 48(3): 434-442 (symposium on the

tenth anniversary of the Affordable Care Act).

Sage WM, Boothman RC, Gallagher TH. Another Medical Malpractice Crisis? Try Something Different. *JAMA* 2020; 324(14): 1395-1396. https://jamanetwork.com/journals/jama/fullarticle/2770929?guestAccessKey=08113fb2-ab8d-4b76-9f2f-4ab7c984dd1b&utm_source=jps&utm_medium=email&utm_campaign=author_alert-jamanetwork&utm_content=author-author_engagement&utm_term=1m (Sept. 17, 2020).

*White AA, Sage WM, Mazor KM, Gallagher TH, Assessing and Supporting Late Career Practitioners: Four Key Questions. *Joint Commission Journal on Quality and Patient Safety* (published Aug. 26, 2020, available at https://www.jointcommissionjournal.com/article/S1553-7250(20)30183-5/fulltext)

Sage WM, Underhill K. Malpractice Liability and Quality of Care: Clear Answer, Remaining Questions. *JAMA* 2020; 323(4): 315-317 (invited editorial).

*Masoudi FA, Viragh T, Magid DJ, Moghtaderi A, Schilsky S, Sage WM, Goodrich G, Newton KM, Smith DH, Black B. Differential Medicare Payment for Noninvasive Cardiovascular Testing between Provider-based Outpatient and Hospital-based Outpatient Settings: Trends and Relationship with Testing Location, 1999-2015. *JAMA Internal Medicine* 2019: https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2753121 (Oct. 14, 2019).

*Kum H-C, Giannouchos T, Washburn D, Sage WM, Ohsfeldt R. Predictors of Multiple Emergency Department Utilization Among Frequent Emergency Department Users in Three States. *Medical Care* 2019: https://journals.lww.com/lww-medicalcare/Abstract/publishahead/Predictors_of_Multiple_Emergency_Department.98378.aspx) (Oct. 23, 2019).

*Thurman WA, Harrison TC, Garcia AA, Sage WM. The Social Construction of Disability and the Capabilities Approach: Implications for Nursing. *Nursing Forum* 2019; 54(4): 642-649.

*Gallagher TH, Mello MM, Sage WM, Bell SK, McDonald TB, Thomas EJ. Can Communication-and-Resolution Programs Achieve Their Potential? Five Key Questions. *Health Affairs* 2018; 37(11): 1845-1852 (special issue on patient safety).

Sage WM and Laurin JE. If You Would Not Criminalize Poverty, Do Not Medicalize It. *Journal of Law, Medicine, and Ethics* 2018; 46(3): 573-581 (symposium on the medicalization of poverty).

*White AA, Sage WM, Osinska P, Salgaonkar M, Gallagher TH. Patient Safety and the Aging Physician: Insights from Key Stakeholders. *BMJ Quality and Safety* 2018 (published online ahead of print) (available at file:///C:/Users/ws2234/Box%20Sync/Documents/Sage%20.pdfs/Physician%20Ageing%20BMJ%20Quality%20and%20Safety%202018.pd https://qualitysafety.bmj.com/content/qhc/early/2018/09/20/bmjqs-2018-008276.full.pdf?ijkey=RKNjkPNzn6SmH0n&keytype=ref).

*Farmer SA, Moghtaderi A, Schilsky S, Magid D, Sage WM, Allen N, Masoudi FA, Dor A, Black B. Association of Medical Liability Reform with Clinician Approach to Coronary Artery Disease Management. *JAMA Cardiology* 2018; 3(7): 609-618.

Sage WM. Fracking Health Care: The Need to Safely De-Medicalize America and Recover Trapped Value for Its People. *NYU Journal of Law and Liberty* 2017; 11(2): 635-671 (symposium on liberty and US health care)

Sage WM, Hyman DA. Antitrust as Disruptive Innovation in Health Care: Can Limiting State Action Immunity Help Save a Trillion Dollars? 48 *Loyola University Chicago Law Journal* 2017; 48: 723-755 (ABA antitrust symposium).

Sage WM. Minding Ps and Qs: The Political and Policy Questions Framing Health Care Spending. *Journal of Law, Medicine, and Ethics* 2016; 44(4): 559-568 (published in 2017) (symposium on health care in a new administration).

*Sage WM, Harding MC, Thomas EJ. Resolving Malpractice Claims After Tort Reform: Experience in a Self-Insured Texas Public Academic Health System. *Health Services Research* 2016; 51(S3): 2615-2633 (AHRQ special issue on liability and safety).

*Etchegaray JM, Ottosen MJ, Aigbe A, Sedlock E, Sage WM, Bell SK, Gallagher TH, Thomas EJ. Patients as Partners in Learning from Unexpected Events. *Health Services Research* 2016; 51(S3): 2600-2614 (AHRQ special issue on liability and safety).

Sage WM. Assembled Products: The Key to More Effective Competition and Antitrust Oversight in Health Care. *Cornell Law Review* 2016; 101(3): 609-700

*Sage WM, Jablonski JS, Thomas EJ. Use of Non-Disclosure Agreements in Medical Malpractice Settlements by a Large Academic Health Care System. *JAMA Internal Medicine* 2015; 175(7): 1130-1135.

*Sage WM, McIlhattan K. Upstream Health Law. *Journal of Law, Medicine & Ethics* 2014; 42(4): 535-549 (symposium on buying and selling health care) (published in 2015).

Sage WM. Medical Malpractice Reform: When Is It About Money? Why Is It About Time? *JAMA* 2014; 312(20): 2103-2105 (invited editorial).

Sage WM. Our "Patchwork" Health Care System: Melodic Variations, Counterpoint, and the Future Role of Physicians. *Houston Journal of Health Law & Policy* 2014; 14(1): 1-9 (invited foreword to symposium on health system fragmentation).

*Sage WM. Getting the Product Right: How Competition Policy Can Improve Health Care Markets. *Health Affairs* 2014; 33(6): 1076-1082.

*Sage WM, Gallagher TH, Armstrong S, Cohn J, McDonald T, Gale JL, Woodward A, and Mello MM. How Policy Makers Can Smooth the Way for Communication-and Resolution Programs. *Health Affairs* 2014; 33(1): 11-19.

*Sage WM, Hyman DA. Let's Make a Deal: Trading Malpractice Reform for Health Reform. *Health Affairs* 2014; 33(1): 53-58.

*Etchegaray JM, Ottosen MJ, Burress L, Sage WM, Bell SK, Gallagher TH, and Thomas EJ. Structuring

Patient and Family Involvement in Medical Error Event Disclosure and Analysis. *Health Affairs* 2014; 33(1): 46-52.

Sage WM. Putting Insurance Reform in the ACA's Rear-View Mirror. *Houston Law Review* 2014; 51(4): 1082-1113 (invited commentary).

Hyman DA, Sage WM. Medical Malpractice in the Outpatient Setting: Through a Glass, Darkly. *JAMA Internal Medicine* 2013; 173(22): 2069-2070 (invited commentary) (available at http://archinte.jamanetwork.com/article.aspx?articleid=1741890).

Golden JM, Sage WM. Are Human Genes Patentable? The Supreme Court Says Yes and No. *Health Affairs* 2013; 32(8):1343-1345.

Rosenbaum S, Sage WM. Maternity Care and Liability. *Women's Health Issues* 2013; 23-1: e3–e5 (commentary).

Sage WM. Legal and Constitutional Influences on the Implementation of U.S. Health Care Reform. *Journal de Droit, de la Santé, et de l'Assurance Maladie* 2013; 1(1): 7-10.

*Sage WM. Both Symptom and Disease: Relating Medical Malpractice to Health Care Costs. *Forum for Health Economics and Policy* 2012; 15(3): 83-106 (available at http://www.degruyter.com/view/j/fhep.2012.15.issue-3/fhep-2012-0010/fhep-2012-0010.xml?format=INT).

*Paik M, Black BS, Hyman DA, Sage WM, Silver CM. How Do the Elderly Fare in Medical Malpractice Litigation, Before and After Tort Reform? *American Law and Economics Review* 2012; 14(2): 561-600 (available at http://aler.oxfordjournals.org/content/14/2/561.full.pdf+html).

Sage WM. How Many Justices Does It Take to Change U.S. Health Care? Only One, But It Has to Want to Change. *Hastings Center Report* 2012; 42(5): 27-33 (commentary).

Sage WM. Brand New Law! The Need to Market Health Care Reform. *University of Pennsylvania Law Review* 2011; 159(6): 2121-2146 (symposium on the Affordable Care Act).

*Hyman CS, Liebman CB, Schechter C, Sage WM. Interest-Based Mediation of Medical Malpractice Lawsuits: A Route to Improved Patient Safety? *Journal of Health Politics, Policy & Law* 2010; 35(5): 797-828.

*Sage WM. Will Embryonic Stem Cells Change Health Policy? *Journal of Law, Medicine & Ethics* 2010; 38(2): 342-351 (symposium on the stem cell controversy).

*Sage WM. Why the Affordable Care Act Needs a Better Name: 'Americare.' *Health Affairs* 2010; 29(8): 1496-1497.

*Sage WM, Balthazar M, Kelder S, Millea S, Pont S, and Rao M. Mapping Data Shape Community Responses to Childhood Obesity. *Health Affairs* 2010; 29(3): 498-502.

Sage WM. Should the Patient Conquer? *Wake Forest Law Review* 2010; 45(5): 1505-1511 (symposium on a patient-centered health system).

Sage WM and Hyman DA. Combating Antimicrobial Resistance: Regulatory Strategies and Institutional Capacity. *Tulane Law Review* 2010; 84(4): 781-839.

*Arrow K et al. Toward a 21st Century Health Care System: Transition Policies for Health Care Reform. *Annals of Internal Medicine* 2009; 150(7): 493-495 (co-author and member of FRESH-Thinking Work Group).

*Hyman DA, Black B, Silver C, and Sage WM. The Effect of Caps on Non-Economic Damages: Evidence from Texas Medical Malpractice Cases. *Journal of Legal Analysis* 2009; 1(1): 355-409.

Sage WM. Over Under or Through: Physicians, Law, and Health Care Reform. *Saint Louis University Law Journal* 2009; 53(4):1033-1048 (Childress Lecture symposium issue).

Sage WM. Out of the Box: The Future of Retail Medical Clinics. *Harvard Law and Policy Review* 2009; 3: 1-11 (available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2377485)

*Black B, Hyman DA, Silver C, and Sage WM. Defense Costs and Insurer Reserves in Medical Malpractice and Other Personal Injury Cases: Evidence from Texas, 1988–2004. *American Law and Economics Review* 2008; 10(2): 185-245.

*Silver C, Zeiler K, Black BS, Hyman DA, and Sage WM. Malpractice Payouts and Malpractice Insurance: Evidence from Texas Closed Claims, 1990-2003. *Geneva Papers on Risk and Insurance: Issues and Practice* 2008; 33: 177-192.

Kinney ED and Sage WM. Dances With Elephants: Administrative Resolution of Medical Injury Claims by Medicare Beneficiaries. *Indiana Health Law Review* 2008; 5(1): 1-7 (invited comment on lead article).

Sage WM. Relational Duties, Regulatory Duties, and the Widening Gap Between Individual Health Law and Collective Health Policy. *Georgetown Law Journal* 2008; 96(2): 497-522 (symposium on the future of health law).

*Hyman DA, Black BS, Silver C, Sage WM, and Zeiler K. Do Defendants Pay What Juries Award? Post-Verdict Haircuts in Texas Medical Malpractice Cases, 1988-2003. *Journal of Empirical Legal Studies* 2007; 4(1): 3-68.

*Zeiler K, Silver C, Black B, Hyman DA, and Sage WM. Physicians' Insurance Limits and Malpractice Payments: Evidence from Texas Closed Claims, 1990-2003. *Journal of Legal Studies* 2007; 36(2): S9-S45 (published in 2008).

*Sage WM. Legislating Delivery System Reform: A 30,000 ft. view of the 800 lb. gorilla. *Health Affairs* 2007; 26(6): 1553-1556 (25th Anniversary Issue).

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Presentations (2014-present)

Invited Lectures, Testimony, and Conference Presentations

"The Future of Human Rights and Justice-Centered Ethics in Epidemic Response" (UCLA-Texas A&M University joint conference; Los Angeles, CA; November 2023) (co-director and moderator)

"Leadership, Ethics, and Communication in Health Policy" (TAMU James Knight Leadership Fellows Program; Bryan, TX; October 2023)

"Improving Health Policy by Reframing Conversations" (UT Southwestern O'Donnell School of Public Health; Dallas, TX; September 2023)

"Unsticking Health Policy" (Texas A&M Community of Scholars Engagement Evening: College Station, TX; September 2023)

"Public Funds, Public Functions, Private Actors: The Cognitive Dissonance of US Health Law" (Harvard Law-Petrie Flom Center Annual Conference: Cambridge, MA; June 2023)

"Accountability and the Health Professions: Lessons for Health Reform from the Vanderbilt Nurse Case" (46th Annual Health Law Professors Conference: Baltimore, MD; June 2023)

"Patient and Public Accountability for Error and Harm: The Vanderbilt Nurse Case Revisited" (UT Annual Health Lawyers Conference: Houston, TX; April 2023)

"Health Policy Lessons from the COVID-19 Pandemic: The System We Have is Not the System We Thought We Had" (UT Dallas School of Economic, Political, and Policy Sciences: Dallas, TX; March 2023)

"Health Equity and the Medical-Legal Partnership" (MITRE Corporation "HealthLab" Series: Bethesda, MD; March 2023 (via Zoom))

"Workflow, Information, and Payment: Aligning Medical-Legal Partnerships with US Healthcare Delivery" (Yale Law School conference on the future of medical-legal partnership: New Haven, CT; March 2023)

"Observations on Accountability and Improvement from the Vanderbilt Nurse Case" (Collaborative on Accountability and Improvement Seminar Series: Seattle, WA (via Zoom); October 2022)

"Mistrust, Misinformation, Race & COVID-19" (Texas State Bar Health Law Conference; Austin, TX; October 2022)

"The Role of the Courts in Health Policy" (2022 North Texas State of Reform Health Policy Conference: Irving, TX; September 2022)

"Consolidation and Competition" (2022 State of Reform Texas Health Policy Conference: Austin, TX; March 2022)

"Helping Medicine Rethink Its Foundations: A Civics Lesson" (44th Annual Health Law Professors Conference: Boston, MA (via Zoom), June 2021)

"The Relationship Between Law and Ethics in US Health Care: An Introduction and Provocation" (Black-Zandveld Lecture, Texas A&M College of Medicine: College Station, TX (via Zoom), May 2021)

"Medicare-for-All and Post-Pandemic Health Reform" (Texas A&M University School of Law conference on Mostly Non-Pandemic Health Law: Fort Worth, TX (via Zoom), March 2021)

"Media Medicine: Physicians, Law, and Professional Ethics in COVID-19 Reporting" (George Washington University Law School/Milken Institute School of Public Health conference on First Amendment Values in Health Care; Washington, DC (via Zoom); March 2021)

"Reforming Scope of Practice to Meet Community Needs" (Penn Nursing/LDI conference on Expanding Scope of Practice After COVID-19 panel discussion: Philadelphia, PA (via Zoom); November 2020)

"Comments on Right-Skilling Health Professionals: Replacing Government Licensing with Third-Party Certification" (Cato Institute online event; September 2020)

"COVID-19 and US Hospitals: Operational and Policy Issues" (University of Luxembourg Centre for Logistics & Supply Chain Management: Luxembourg (via Zoom); June 2020)

"COVID-19 and U.S. Health Law: Emergency Change or System Reset?" (Wagner School of Public Service WagTalk: New York, NY; April 2020)

"The Ethical Foundations of Medicare-for-All" (Columbia University School of Medicine Bioethics Grand Rounds: New York, NY; January 2020)

"Panel Discussion: Universal Health Care: Can Expanding Public Health Insurance Address Health Disparities?" (NYU Langone Medical Center conference on the politics of health, disparities, and equity: New York, NY; October 2019)

"Expanding Access to Public Programs" (American University conference on Next Steps in Health Reform: Washington, DC; October 2019)

"The Future of Nursing" (ASLME 42nd Annual Health Law Professors Conference: Chicago, IL; June 2019)

"The Innovative Potential of Medicare-for-All" (American Society of Neuroradiology Annual Meeting: Boston, MA; May 2019) (J. Arliss Pollock Memorial Award)

"Medicare-for-All" (University of Texas Health and Humanities Institute: Austin, TX; April 2019)

"Escaping Medicare's Gilded Age: The Innovative Potential of Medicare-for-All. (BioLaw Lapalooza 3.0: Stanford, CA; March 2019)

"Ethical and Legal Obligations to Disclose and the Communication and Resolution Program (CRP) Movement" (Federation of State Medical Boards Annual Counsel Meeting: Austin, TX; November 2018)

"AI, Robotics, and the Practice of Medicine" (Panel Discussion, Yale Law School Conference on the Law & Policy of AI, Robotics & Telemedicine in Health Care: New Haven, CT; November 2018)

"The On-Again Off-Again ACA" (Austin Area Research Organization: Austin, TX; October 2018)

"The Medicalization of Poverty" (ASLME 41st Annual Health Law Professors Conference: Cleveland, OH; June 2018)

"Keynote Address: Regulation and Competition in the US Heath Care System (Netherlands Health Authority Conference on the Law and Policy of Healthcare Financing: Utrecht, NL; June 2018)

"Safety and Late Career Practitioners: Lessons from Regulating Physicians in Training" (Accelerating the Development of Late Career Practitioner Programs at US Healthcare Institutions, All-Stakeholder Meeting: Seattle, WA; May 2018)

"How Law Constrains Policy in US Health Reform" (Department of Pediatrics Grand Rounds, Dell Medical School: Austin, TX; May 2018)

"Fracking Health Care" (Department of Surgery Grand Rounds, Dell Medical School: Austin, TX; May 2018)

"How Law Constrains Policy in US Health Reform" (Nell Hodgson Woodson School of Nursing Health Policy Series: Atlanta, GA; April 2018)

"Fracking Health Care" (Alan Ross Hawley Distinguished Visitorship and Lecture Series, University of Iowa College of Law: Iowa City, IA; April 2018)

"Burning Issues in Health Policy: Commentary" (Emory University Healthcare Innovation Symposium XXIII: Atlanta, GA; March 2018)

"De-medicalizing Health Care" (Stanford Law School "Biolawpalooza": Stanford, CA; March 2018)

"Keynote Address: Boosting Clinical and Social Value in U.S. Health Reform" (American Society of Phlebology Annual Meeting: Austin, TX; November 2017)

"Fracking Healthcare" (University of Illinois-Carle Clinic Conference on the Medicalization of Poverty: Champaign, IL; November 2017)

"Teaching Leadership Skills to Medical Students: A Progress Report from the Pioneers" (National Academy of Medicine Annual Meeting: Washington, D.C.; October 2017)

"Why We Aren't There: Health Law Constraints on Health Policy Solutions" (American Enterprise Institute: Washington, D.C.; September 2017)

"Update on Health Care Reform" (Austin Area Research Organization Board Meeting: Austin, TX; September 2017)

"Release and Repurpose: Solving the Social and Economic Problem of Low-Value Medicine" (40th Annual Health Law Professors Conference: Atlanta, GA; June 2017)

"The AHA and the 'AHCA'" (Dell Medical School Brown Bag Lunch Series: Austin, TX; May 2017)

"Ethics in the Era of Rapid Innovation and Entrepreneurship in Healthcare" (McCombs School of Business Innovation in Healthcare Delivery Systems Symposium 2017: Austin, TX; April 2017)

"Resolving Malpractice Claims after Tort Reform: Experience in a Self-Insured Texas Public Academic Health System" (McCombs School of Business Innovation in Healthcare Delivery Systems Symposium 2017: Austin, TX; April 2017)

"What Worked and Didn't Work in Obamacare?" (Delta Omega Honor Society Distinguished Lecture Series, Texas A&M School of Public Health: College Station, TX; April 2017)

"The Arc of Health Reform" (Department of Medicine Grand Rounds, UCLA Health: Los Angeles, CA; March 2017)

"Recover and Repurpose: Solving the Social and Economic Problem of Low-Yield Medicine (NYU Classical Liberal Institute Conference on Health Innovation: New York, NY; February 2017)

"Beyond Financing: Keeping "Care" and "Health" in Health Care Reform" (American Bar Association Washington Health Law Summit: Washington, DC; December 2016)

"Healthcare Consolidation: How Regulation Drives Competition" (PhRMA State Medical Society Meeting 2016: Denver, CO; October 2016)

"Legal Influences on Health Care Innovation" (Ulahealth conference on Blockchain-based health care innovation: Austin, TX; October 2016)

"Health System Transformation and National Health Reform: Legal Barriers and Generational Opportunities" (National Academy of Medicine Health Policy and Health Care Systems Annual Interest Group Meeting: Washington, DC; October 2016)

"Responding to Patient Harm using "Communication-and-resolution" Principles: Challenges and Opportunities (American College of Obstetricians and Gynecologists, Texas region annual meeting: The Woodlands, TX; September 2016) (ethics keynote)

"And Not *Or*: The Conjunctive Challenges of Health Reform" (University of Pennsylvania Symposium and Tribute to Richard A. "Buz" Cooper, MD: Philadelphia, PA; September 2016) (afternoon keynote)

"U.S. Health Policy and the Future of Advanced Practice Nursing" (Penn School of Nursing conference on nursing workforce policy: Philadelphia, PA; September 2016)

"Addressing Hidden Regulatory Barriers to Effective Competition in Health Care" (American Bar Association/Loyola University Chicago conference on antitrust and consumer protection in health care: Chicago, IL; September 2016)

"Improving Communication with Patients in Cases of Error or Serious Adverse Events" (conference organizer and principal presenter for Universite Paris Descartes/Assistance Publique Hopitaux de Paris Workshop: Paris, France; June 2016)

"The Current Status and Future of 'Obamacare'" (Sciences Po, Institut Droit et Sante – Inserm public lecture: Paris, France; June 2016)

"Re-Regulating Health Care for the 'Triple Aim' Generation of Professionals, Policymakers, and Patients" (Federation of State Medical Boards Annual Meeting: San Diego, CA; April 2016)

"Professional Speech and the First Amendment" (Northeastern University School of Law conference on the Future of Public Health: Boston, MA; April 2016)

"Legal and Policy Context for Value-Based Care Redesign" (Brown University Department of Orthopedic Surgery Grand Rounds: Providence, RI; March 2016)

"Keynote address: U.S. Health Policy, the ACA, and the Future of Advanced Practice Nursing" (Texas Nurses Association APRN Legislative Day: Austin, TX; February 2016)

"Keynote address: Health Policy and the Changing Role of Clinical Practice Guidelines" (Dell Medical School Department of Women's Health Clinical Guidelines Forum: Austin, TX; February 2016)

"Health Law at War with Health Policy" (Texas A&M University School of Public Health: College Station, TX; January 2016)

"State Medical Boards: Legal, Institutional, and Generational Changes" (University of Washington School of Medicine conference on developing ethically sound regulatory strategies for medical injuries: Seattle, WA; December 2015)

"ACOs, New Health Care Delivery Models, and Physicians: The Promise of Generational Change" (Yale Law School and Yale School of Management conference on The New Health Care Industry: New Haven, CT; November 2015)

"Issues in Health Economics and Health Policy" (University of Texas Plan II Honors Pre-Medical Society: Austin, TX; October 2015)

"Beyond Revenue and Compliance: The ACA and Strategic Legal Issues for Texas Teaching Hospitals" (Teaching Hospitals of Texas Annual Health Law Seminar: Austin, TX; October 2015)

"Adding Value to Health Care" (Accordion Health Employer Health Conference 2015: Austin, TX; June 2015)

"Why Aren't We There Already? Centering Health Law on the ACA's Care Delivery and Population Health Goals" (Health Law Professors Conference: St. Louis, MO; June 2015)

"Competition that Adds Value: Big Picture Challenges in Health Law & Policy" (American Academy of Orthopaedic Surgeons course on Shifting from Volume to Value: Preparing your Practice for Health Reform: Washington, DC; May 2015)

"Belaboring Delivery System Reform" (University of Connecticut Insurance Law Center Conference on the 5th Anniversary of the Affordable Care Act: Hartford, CT; April 2015)

"Upstream Health Law" (McCombs School of Business Annual Conference on Innovation in Health Care Delivery Systems: Austin, TX; April 2015)

"The Affordable Care Act in 2015: Implications of Political Change" (American Association of Colleges of Pharmacy Interim Meeting: Austin, TX; February 2015)

"Adding Value by Improving Competition in Health Care" (Philosophical Society of Texas 177th Anniversary Meeting: Tyler, TX; February 2015)

"Beyond FDA: A Diversified Information Policy for 'Unproven' Treatments" (Texas Law Review Symposium on Science Challenges for Law and Policy: Austin, TX; January 2015)

"Rethinking the Product: A Path to More Effective Competition in Health Care" (Rice University Baker Institute for Public Policy: Houston, TX; December 2014)

"Health Care in the United States: How Public Regulation Drives $3 Trillion of Private Competition" (European University Institute conference on Antitrust Law in Healthcare: Florence, Italy; November 2014)

"Unpacking the Regulation of Professional Speech (Yale Law School conference on Public Health in the Shadow of the First Amendment: New Haven, CT; October 2014)

"Keynote address: Consolidation and Competition Policy" (Healthcare Financial Management Association Thought Leadership Retreat: Washington, DC; October 2014)

"Communication and Resolution Programs: Policy Goals and Legal Issues" (Washington Medical Quality Assurance Commission Annual Educational Conference: Olympia, WA; October 2014)

"The Effects of Obamacare" (National Latino Law Student annual meeting: Austin, TX; September 2014)

"Disclosure and Apology: A Win-Win for Patient Safety and Medical Liability" (Alliance for Health Reform U.S. Capitol Briefing: Washington, DC; July 2014)

"Engaging Patients as Partners in Error Disclosure to Improve Patient Care: Legal Issues" (AHRQ-UT Health Science Center-Houston: Houston, TX; June 2014)

"Let the People In: Scope of Practice Reform in Texas" (Texas Public Policy Foundation Issue Briefing: Austin, TX; May 2014)

"Getting the Product Right: How Competition Policy Can Improve Health Care Markets" (Health Affairs Briefing, Provider Consolidation in Health Care: Washington, DC; May 2014)

"Clinical Trials Data Sharing, Litigation, and the First Amendment" (Presentation to the Institute of Medicine Committee on Strategies for Responsible Sharing of Clinical Trial Data: Washington, DC; April 2014) (via webcam)

"Improving Health Care Competition by Getting the Product Right" MD Anderson Cancer Center Institute for Cancer Care Innovation: Houston, TX; April 2014)

"Healthy Competition?" (Bipartisan Congressional Health Policy Conference: Houston, TX; March 2014)

"Obamacare: Do the Benefits Outweigh the Costs?" (Adam Smith Society Debate, McCombs School of Business: Austin, TX; January 2014)

<u>Seminars and Workshops</u>
"Health Policy Lessons from the COVID-19 Pandemic" (Bush School of Government and Public Service; College Station, TX; December 2022)

"Comments on 'Fiscal Waivers' in Federal Health Programs (Emory Law School Federal Funding Issues Workshop: via Zoom; November 2020) (with Keegan Warren-Clem)

"Race, Health Justice, and COVID-19" (University of Texas Law School workshop series: via Zoom; November 2020)

"Comments on Expressive Law and Medicaid Work Requirements" (Seton Hall Law School Health Law Works-in-Progress Retreat: Newark, NJ; February 2020)

"Medicare-for-All as Principled Health Reform" (Hastings Center Scholars Workshop: Garrison, NY; November 2019)

"Adding Principle to Pragmatism: The Transformative Potential of Medicare-for-All" (NYU School of Law Faculty Workshop, New York, NY; November 2019)

"If You Would Not Criminalize Poverty, Do Not Medicalize It" (NYU Langone School of Medicine, Department of Population Health Seminar: New York, NY; March 2019)

"The Innovative Potential of Medicare-for-All" (NYU School of Law, Engelberg Center Workshop: New York, NY; March 2019)

"If You Would Not Criminalize Poverty, Do Not Medicalize It" (Duke Law School Health Law & Policy Workshop: Durham, NC; November 2018)

"If You Would Not Criminalize Poverty, Do Not Medicalize It" (University of San Diego Law School Faculty Workshop: San Diego, CA; October 2018)

"Fracking Healthcare" (Emory Law School Faculty Workshop: Atlanta, GA; April 2018)

"Fracking Healthcare" (Rollins School of Public Health, Department of Health Policy & Management Faculty Workshop: Atlanta, GA; March 2018)

"Fracking Healthcare" (UNLV Law & Medicine Workshop: Las Vegas, NV; February 2018)

"Why We Aren't There Yet: Recognizing and Reducing Legal Barriers to High Value Care" (Dell Medical School Department of Surgery Faculty Meeting: Austin, TX; November 2017)

"Relating Health Law to Health Policy" (UT Law School Bookfest: Austin, TX; October 2017)

"Health Law Constraints on Health Policy Solutions" (Texas A&M University Bush School of Government seminar series: College Station, TX; October 2017)

"Fracking Healthcare" (Harvard Law School Petrie-Flom Center Workshop Series: Cambridge, MA; September 2017)

"Medical-Legal Partnerships" (UT Law School Faculty Drawing Board Presentation: Austin, TX; March 2017)

"Recover and Repurpose: Engineering the De-Medicalization of US Social Policy" (UCLA Law School faculty workshop: Los Angeles, CA; March 2017)

"Legal, Professional, and Generational Perspectives on US Health Policy Challenges" (Emory Health System clinical leadership meeting: Atlanta, GA; March 2016)

"Health Law Barriers to Health Policy Solutions" (Weill Cornell Department of Health Policy faculty seminar: New York, NY; March 2016)

"Regulatory Theory and Tobacco Control, or Why Dancers Smoke" (University of Texas School of Public Health tobacco research center seminar: Austin, TX; December 2015)

"Relating Health Law to Health Policy" (University of Arizona interdisciplinary seminar on regulation: Tucson, AZ; December 2015)

"Relating Health Law to Health Policy" (Emory Law School Faculty Workshop: Atlanta, GA; November 2015)

"Relating Health Law to Health Policy" (Cornell Law School Faculty Workshop: Ithaca, NY; November 2015)

"Health Law and Health Policy: A Frictional Account" (Southern Methodist University Law School Faculty Workshop: Dallas, TX; October 2015)

"Rethinking the Product: A Path to More Effective Competition in Health Care" (Emory Law School Faculty Workshop: Atlanta, GA; September 2014)

"Improving Competition Policy for Health Care Markets" (University of Texas School of Law Faculty Workshop: Austin, TX; February 2014)

Exhibit B

LITERATURE:

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DEPOSITIONS AND TRANSCRIPTS:

30(b)(6) Deposition and Exhibits of Donald Hicks Taken on 6.28.18 and 6.29.18
30(b)(6) Deposition and Exhibits of John Hopkins Taken on 8.16.18, 8.17.18, 10.17.18, 11.05.18
30(b)(6) Deposition and Exhibits of Joshua Muscat Taken on 9.25.18
30(b)(6) Deposition and Exhibits of Julie Pier Taken on 9.12.18 and 9.13.18
30(b)(6) Deposition and Exhibits of Linda Loretz Taken on 7.17.18, 10.1.18 and 10.2.1830(b)(6) Deposition and Exhibits of Margaret Gurowitz Taken on 7.12.18
30(b)(6) Deposition and Exhibits of Mark Pollack Taken on 8.29.18 30(b)(6) Deposition and Exhibits of Pat Downey Taken on 8.7.18 and 8.8.1830(b)(6) Deposition and Exhibits of Robert Glenn Taken on 10.18.18
30(b)(6) Deposition and Exhibits of Susan Nicholson Taken on 7.26.18 and 7.27.1830(b)(6) Deposition and Exhibits of Tina French Taken on 8.15.18
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Deposition testimony and exhibits of Lorena Telofski (February 24, 2021)
Deposition testimony and exhibits of Susan Nettesheim (April 16, 2021)
Deposition testimony and exhibits of Steven Mann (April 8 and 28, 2021)
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Exhibit C

William Sage, MD, JD
Medical Legal Testimony in last 4 years

Date: September 23, 2021
Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Product Liability Litigation MDL No. 2738

Hourly Rate: $900/hour